

Exhibit 14

Mark Krekeler, Ph.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON	:	MDL NO. 2592
TALCUM POWDER PRODUCTS	:	16-2738 (FLW) (LGH)
MARKETING, SALES PRACTICES	:	
AND PRODUCTS LIABILITY	:	
LITIGATION	:	
	:	
THIS DOCUMENT RELATES TO:	:	
ALL CASES	:	
	:	

Videotaped Deposition of

MARK KREKELER, Ph.D.

Taken: By the Defendants
Pursuant to Notice

Date: January 25, 2019

Time: Commencing at 9:16 a.m.

Place: Hampton Inn
375 South College Avenue
Oxford, Ohio 45056

Before: Susan M. Gee, RMR, CRR
Notary Public - State of Ohio
and
Melinda Sindiong, CLVS

Mark Krekeler, Ph.D.

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14 EXHIBITS

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16 NUMBER DESCRIPTION PAGE

17 1 11/16/18 Rule 26 Expert Report of 13

18 Mark Krekeler, Ph.D.

19 2 1/17/19 Rule 26 Addendum to the 13

20 Expert Report of Mark Krekeler, Ph.D.

21 3 IRSST report R-755 82

22 4 IC 8757 Bureau of Mines Information 86

23 Circular/1977

24 5 IARC Monographs on the Evaluation of 91

25 Carcinogenic Risks to Humans, Vol. 93

6 U.S. Department of Health and Human 109

Services Toxicological Profile for

Asbestos 9/2001

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1 EXHIBITS

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4 7 NIOSH Current Intelligence Bulletin 62 116

5 Asbestos fibers and Other Elongate

6 Mineral Particles: State of the Science

7 and Roadmap for Research, Revised Edition

8 State of Montana, Bureau of Mines and 120

9 Geology, Reconnaissance Geology of

10 Southernmost Ravalli County, Montana,

11 by Richard B. Berg

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13 9 International Geology Review, The 140

14 Serpentine Multisystem Revisited:

15 Chrysotile is Metastable

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17 10 Windsor Minerals, Inc. 144

18 Geology of the Talc Mine at East

19 Johnson, Vermont

20 Bates JNJ000272469 - 668

21 11 Using the geologic setting 160

22 of talc deposits as an indicator

23 of amphibole asbestos content by

24 Bradley S. Van Gosen, et al.

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12 Geology, Asbestos and Health by 160

13 Malcolm Ross, December 1974

14 Letter from RJ Lee Group dated 5/16/16 161

15 Bates JNJ 000521616 - 638

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17 14 Krekeler Deposition Italian Documents 164

18 Various Bates numbers

19 15 Department of the Interior Geological 174

20 Survey Circular 95 - Talc

21 Investigations Vermont Preliminary

22 Report

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24 16 Talc Resources of the United States 177

25 Geological Survey Bulletin 1167

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<p style="text-align: right;">Page 7</p> <p>1 VIDEOGRAPHER: We are now on the record.</p> <p>2 My name is Melinda Sindiong, CLVS. I'm</p> <p>3 videographer for Golkow Litigation Services.</p> <p>4 Today is January 25th, 2019. The time is 9:16.</p> <p>5 The video deposition is being held in Oxford,</p> <p>6 Ohio, in the matter of Johnson & Johnson Talcum</p> <p>7 Powder Products Marketing Sales Liability</p> <p>8 Litigation. This is for the United States</p> <p>9 District Court of the District of New Jersey.</p> <p>10 The deponent is Mark Krekeler, M.D.</p> <p>11 Will counsel please identify yourselves</p> <p>12 and the parties you represent?</p> <p>13 MS. SCOTT: My name is Carmen Scott. I'm</p> <p>14 with Motley Rice, for the plaintiffs.</p> <p>15 MS. O'DELL: Leigh O'Dell, Beasley Allen,</p> <p>16 for the plaintiffs.</p> <p>17 MS. EMMEL: Jennifer Emmel, Beasley</p> <p>18 Allen, for the plaintiffs.</p> <p>19 MR. LAPINSKI: Daniel Lapinski, Wilentz</p> <p>20 law firm, for the plaintiffs.</p> <p>21 MR. FROST: Jack Frost, Drinker Biddle &</p> <p>22 Reath, on behalf of Johnson & Johnson.</p> <p>23 MS. ROSE: Nina Rose, Skadden, Arps, on</p> <p>24 behalf of Johnson & Johnson.</p> <p>25 MR. FERGUSON: Ken Ferguson, Gordon &</p>	<p style="text-align: right;">Page 9</p> <p>1 University. I hold an appointment where my tenure is</p> <p>2 held on the Oxford campus in the department of geology,</p> <p>3 and my teaching the -- I work at the Hamilton campus as</p> <p>4 well.</p> <p>5 Q. And just so the record is clear, Miami</p> <p>6 University, there are two. We're at the one in Ohio,</p> <p>7 right?</p> <p>8 A. To my knowledge, there's only one Miami</p> <p>9 University.</p> <p>10 Q. The other one's University of?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. All right.</p> <p>13 A. Miami was founded in 1809.</p> <p>14 Q. And have you ever been deposed before?</p> <p>15 A. No, I have not been deposed before.</p> <p>16 Q. Okay. Have you ever testified before?</p> <p>17 A. No, I have not testified before.</p> <p>18 Q. All right. Real quick, I'll go over some</p> <p>19 ground rules. I'm sure your counsel has told you this,</p> <p>20 but the number one most important thing is everything</p> <p>21 we're saying today is being written down by the court</p> <p>22 reporter who's to my left. So because of that, we have</p> <p>23 to make sure we verbalize everything. Uh-huh, huh-uh,</p> <p>24 nods of the head, pointing, things like that don't show</p> <p>25 up very well in written word.</p>

3 (Pages 6 to 9)

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<p>1 A. Very good.</p> <p>2 Q. So we just need to make sure that, you</p> <p>3 know, we're verbalizing everything.</p> <p>4 Second thing is, and I guarantee we'll</p> <p>5 get in trouble for this at some point. It's very hard</p> <p>6 for the court reporter to write down when both of us are</p> <p>7 talking at the same time. I'm not saying we're doing it</p> <p>8 in a rude way but just normal human conversation.</p> <p>9 Eventually, you'll pick up what the end of my question</p> <p>10 is. I'll pick up the end of your answer, and we'll just</p> <p>11 start naturally talking over each other. We've got to</p> <p>12 be really careful about that, you know, make sure she</p> <p>13 can write it down.</p> <p>14 At some points during the deposition,</p> <p>15 your counsel may object or other people in the room may</p> <p>16 object. Allow time to give counsel, you know, to put</p> <p>17 their objections on. Once they're done, unless you're</p> <p>18 instructed otherwise by your counsel, you have to answer</p> <p>19 my question.</p> <p>20 The other thing is, if you answer my</p> <p>21 question, I'm going to understand you assumed it or</p> <p>22 understood it. So if you don't understand what I'm</p> <p>23 asking, you need clarification, let me know. If there</p> <p>24 is, you know, something you need for me to work out, I'd</p> <p>25 rather work it out than have you answer something that,</p>	<p>1 just say it again and agree on it or -- I'm unclear.</p> <p>2 I've never done this before.</p> <p>3 BY MR. FROST:</p> <p>4 Q. Sure. So to the extent we can, just</p> <p>5 listen to my question and answer the question, yeah, as</p> <p>6 I've asked it. What shows up on the screen is called</p> <p>7 phonetic, so sometimes the words converted over by the</p> <p>8 computer will be incorrect, and ultimately, when they</p> <p>9 come and transfer it for the final transcript, it will</p> <p>10 change.</p> <p>11 So these are sort of there as a guide, if</p> <p>12 we can't remember what we're talking about a couple</p> <p>13 minutes ago, to look back. But this is not the official</p> <p>14 record. The official record will be what's on the</p> <p>15 video, and then, ultimately, what's in the transcript,</p> <p>16 which might end up being a little different than what's</p> <p>17 on the screen.</p> <p>18 A. Okay. And because -- so a third party</p> <p>19 would go and transcribe what's on the video?</p> <p>20 Q. So I'm not sure at the end, yeah.</p> <p>21 A. So if there's something garbled on here,</p> <p>22 someone else does that?</p> <p>23 Q. Yes. That's correct.</p> <p>24 A. So they don't come back to me or --</p> <p>25 Q. No. You don't need to worry about that.</p>
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<p>1 you know, you and I are talking at different places.</p> <p>2 The only other thing, too, I don't want</p> <p>3 you to guess here today, and if you're guessing or</p> <p>4 making an estimate, just let us know. And, you know,</p> <p>5 but if it's a wild guess, I don't know, I don't</p> <p>6 remember, those are perfectly fine answers.</p> <p>7 And other than that, if you need a break</p> <p>8 at any time, let us know. If there's a question</p> <p>9 pending, you've got to answer the question first, but</p> <p>10 we're here on your schedule, so -- and we'll try to</p> <p>11 break every hour, hour and a half or so, but if you need</p> <p>12 to break in between, you know, just let us know, and</p> <p>13 we'll stop.</p> <p>14 A. Can I ask a question?</p> <p>15 Q. Sure.</p> <p>16 A. So I've never done this before. I've</p> <p>17 never been deposed, and I noticed early on, when the</p> <p>18 videographer was making some statements, that the</p> <p>19 statements that I heard were not recorded accurately on</p> <p>20 this. So the word was "demotion."</p> <p>21 MS. SCOTT: You don't need to worry about</p> <p>22 that.</p> <p>23 A. So but my question is, is if I go -- if I</p> <p>24 use this to read your question, how do I know a word's</p> <p>25 not -- how do we make sure that word is right? Do we</p>	<p>1 That's done somewhere else.</p> <p>2 A. Okay. Yeah. I don't -- I don't know.</p> <p>3 Q. No. That's okay. It's a fair question.</p> <p>4 But --</p> <p>5 VIDEOGRAPHER: Sorry. If I can interject</p> <p>6 as well, you're talking with your hands, and it</p> <p>7 does get in the shot.</p> <p>8 MR. FROST: Oh, mine does?</p> <p>9 VIDEOGRAPHER: Yes.</p> <p>10 THE WITNESS: Okay. Sorry.</p> <p>11 VIDEOGRAPHER: Thank you.</p> <p>12 MR. FROST: All right. So if I can mark</p> <p>13 a couple exhibits to begin. I'll mark this as</p> <p>14 Exhibit 1.</p> <p>15 (Exhibit 1 was marked for</p> <p>16 identification.)</p> <p>17 MR. FROST: I'll mark this as Exhibit 2.</p> <p>18 THE WITNESS: Does it matter which copy?</p> <p>19 MS. SCOTT: You can take a look at</p> <p>20 whichever you're more comfortable with. They're</p> <p>21 the same.</p> <p>22 MR. FROST: I imagine they're the same,</p> <p>23 right?</p> <p>24 (Exhibit 2 was marked for</p> <p>25 identification.)</p>

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<p>1 BY MR. FROST:</p> <p>2 Q. All right. In front of you marked as</p> <p>3 Exhibits 1 and 2 are your expert report that's dated</p> <p>4 November 16th, 2018, and then Exhibit 2 is your</p> <p>5 supplemental report dated January 17th, 2019; is that</p> <p>6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. Are these the only two reports that</p> <p>9 you've written in this case?</p> <p>10 A. Yes.</p> <p>11 Q. Now, you understand you've been</p> <p>12 designated by the plaintiffs in this case in the Johnson</p> <p>13 & Johnson talc MDL?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Can you explain to me what, or</p> <p>16 define what your area of expertise is?</p> <p>17 A. Yes. So my undergraduate degree was in</p> <p>18 geology, and since my freshman year, I've been working</p> <p>19 with clay materials and clay intervals. My degree is</p> <p>20 in -- my undergraduate degree is a bachelor's of science</p> <p>21 in geology, and so that entailed field work. And,</p> <p>22 actually, I think since my freshman year, I've been</p> <p>23 doing powder x-ray diffraction. My master's was on,</p> <p>24 also, a clay rich rock, bentonite, so -- and then in --</p> <p>25 I finished that degree in '98.</p>	<p>1 phyllosilicates as well. And, basically, I worked with</p> <p>2 industrial mineral materials, mine materials, and then</p> <p>3 my time at Miami University, I've also worked with</p> <p>4 synthetic minerals and natural minerals.</p> <p>5 So my training as a Ph.D. student was to</p> <p>6 look at the phyllosilicate minerals as a whole. So</p> <p>7 mineralogy has evolved significantly in that we think of</p> <p>8 minerals as sort of a system, and we look at things at</p> <p>9 how they're interrelated. And that's -- so, basically,</p> <p>10 I've had some -- my degree is in geotechnical</p> <p>11 engineering and environmental earth science, so I have a</p> <p>12 few engineering classes. And then I've collaborated and</p> <p>13 worked with several mineral companies. My Ph.D. was</p> <p>14 sponsored by a mineral company, in part.</p> <p>15 Q. So long story short, would you define</p> <p>16 your area of expertise as mineralogy?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And the two reports in front of</p> <p>19 you, do those reflect all the opinions you plan to give</p> <p>20 in this case or intend to give in this case?</p> <p>21 A. Well, again, I'm legally not familiar</p> <p>22 with the process, but I think I -- currently, this is my</p> <p>23 opinions. If something new comes up and I'm asked, I</p> <p>24 would...</p> <p>25 Q. Okay. I guess a better way to ask that</p>
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<p>1 Then my Ph.D. was in mineralogy and</p> <p>2 specifically phyllosilicate mineralogy and looking at</p> <p>3 the impurities and materials associated with</p> <p>4 phyllosilicates. My dissertation was on</p> <p>5 palygorskite-sepiolite minerals and smectite minerals.</p> <p>6 My Ph.D. advisor was Steve Guggenheim, who essentially</p> <p>7 is the North American expert in crystallography for</p> <p>8 phyllosilicates.</p> <p>9 And, then, so I finished that degree in</p> <p>10 2003. Throughout my degrees, I think my first</p> <p>11 consulting job was a project with Amoco when I was an</p> <p>12 undergrad doing x-ray diffraction, looking at clays from</p> <p>13 Trinidad through my advisor, Warren Huff. But through</p> <p>14 that period of time, I did occasional consulting</p> <p>15 projects, largely with powder x-ray diffraction and</p> <p>16 sometimes electron microscopy.</p> <p>17 Then I did not do a postdoc. There were</p> <p>18 two mineralogy positions available nationwide when I</p> <p>19 graduated. My graduation year was 2003. I then got one</p> <p>20 of those positions at George Mason University, and I was</p> <p>21 hired in a department of environmental science and</p> <p>22 policy. And my research there, I was specifically</p> <p>23 teaching mineralogy. Then my research was centered</p> <p>24 around mineralogy.</p> <p>25 I produced a few patents relating to</p>	<p>1 question --</p> <p>2 A. Sorry. I'm unclear. I'm not familiar.</p> <p>3 Q. Yeah. That's okay. As we sit here</p> <p>4 today, do you intend to offer any opinions in this case</p> <p>5 that aren't reflected in either of these two reports?</p> <p>6 A. No. The reports are what I am using.</p> <p>7 Q. And were you asked to render any reports</p> <p>8 by your counsel that you did not or are not included in</p> <p>9 those reports?</p> <p>10 MS. SCOTT: Objection. You can answer.</p> <p>11 BY MR. FROST:</p> <p>12 Q. You can answer.</p> <p>13 A. Oh, I can answer? So, if I remember</p> <p>14 correctly, with the deposition notice, it was requested</p> <p>15 that reports or documents I prepared relating to, I</p> <p>16 think, all talc cases were requested. So there's one</p> <p>17 report that I gave to them from another case that I'm</p> <p>18 involved in.</p> <p>19 Q. Okay. So you're currently involved in</p> <p>20 another talc case or is this an older case?</p> <p>21 A. This is a current case.</p> <p>22 Q. And it's a talc case?</p> <p>23 A. It is a talc-related case, yes.</p> <p>24 Q. Is it a case against Johnson & Johnson?</p> <p>25 A. I believe it's a case against Imerys.</p>

5 (Pages 14 to 17)

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<p style="text-align: right;">Page 18</p> <p>1 Q. Against Imerys? Do you know what the 2 case is called or where it's venued? 3 A. I don't remember offhand. The law firm 4 is Waters & Kraus. 5 Q. That's who retained you? 6 A. Yes. 7 Q. Do you know what state it's in? 8 A. The law firm is in Texas. I think the 9 case is in Texas. 10 Q. And what have you been asked to do in 11 that case? 12 MS. SCOTT: I'm going to object to the 13 extent that I'm not aware of what his role is in 14 that case. 15 MR. FROST: Sure. 16 MS. SCOTT: And I'm not sure he knows 17 what's going on and, you know, the extent of 18 the -- whether he's been disclosed in that case 19 or not. 20 MR. FROST: Okay. 21 MS. SCOTT: So I'm going to object to any 22 questions on that. 23 MR. FROST: All right. We'll reserve our 24 right to come back. 25 MS. SCOTT: Sure.</p>	<p style="text-align: right;">Page 20</p> <p>1 cite throughout the report? 2 A. Yes. 3 Q. The piece of literature, things like 4 that? 5 A. Yes. 6 Q. Okay. Other than documents, books, 7 literature, et cetera, that are already included in your 8 report, have you brought anything else with you today? 9 A. No. I believe just what is in the 10 report. 11 Q. Okay. We're also going to probably send 12 a request for, you know, a copy of the report written on 13 the other case as well. It seems like it was turned 14 over to counsel. 15 MS. O'DELL: No. You misunderstood. 16 It's not been turned over to counsel. 17 MR. FROST: It hasn't been turned over to 18 you guys. 19 MS. O'DELL: We don't have any 20 information about that case. 21 MR. FROST: Oh, okay. 22 MS. O'DELL: Yeah. So if you have any 23 questions about that, you need to talk to Waters 24 & Kraus or whoever else is involved. 25</p>
<p style="text-align: right;">Page 19</p> <p>1 BY MR. FROST: 2 Q. Have you brought that report that you 3 drafted in that case with you today? 4 A. I don't know. 5 Q. Okay. Did you bring anything with you -- 6 I'll start. So there seems to be a table of stuff next 7 to you. Is that a fair way to describe that? 8 A. Yes. 9 Q. And what, generally, is that stuff? Like 10 what's in the binders and things like that? 11 A. So, generally, those are documents that 12 were provided when I requested them, and those documents 13 are from the companies. 14 Q. Are those all the documents that are 15 listed in your materials-relied-upon list at the end of 16 your report? 17 A. Yes. 18 Q. Is there anything in those binders that 19 isn't otherwise reflected on the list in your reports? 20 A. I'm sorry? 21 Q. I can reask it if it's easier. 22 A. Is there anything in those binders that 23 isn't otherwise reflected on the list? I have books 24 that are also included in the report. 25 Q. Okay. Those are the various books you</p>	<p style="text-align: right;">Page 21</p> <p>1 BY MR. FROST: 2 Q. So before, when you said you'd given the 3 report to counsel, you're talking about Waters & Kraus, 4 not -- 5 A. I don't recall specifics. 6 Q. All right. Have you turned that report 7 at all over to any of your attorneys who are here today 8 or anybody who works for them, their law firms, if you 9 can recall? 10 A. I don't remember specifics. 11 Q. Okay. Do you recall when you were 12 retained in that case? 13 A. In the other case? 14 Q. Yes. 15 A. It was about the same time as this case. 16 Q. Do you recall when that was? 17 A. Basically, I want to say it was towards 18 the end of December of 2017, but -- so that's when we 19 talked, and then I think it was like late January, maybe 20 February, when I actually started reviewing documents 21 for that case. 22 Q. Have you generated any invoices for your 23 work in this case yet? 24 A. I'm sorry. Are you referring to -- 25 Q. For this, what we're here for today, the</p>

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<p style="text-align: right;">Page 22</p> <p>1 Johnson & Johnson MDL case.</p> <p>2 A. Yes. I'm up to date with invoices.</p> <p>3 Q. And did you bring any of those invoices</p> <p>4 with you?</p> <p>5 MS. SCOTT: Counsel, those were provided</p> <p>6 previously about a week ago by email.</p> <p>7 MR. FROST: All right.</p> <p>8 BY MR. FROST:</p> <p>9 Q. But other than that, there's nothing, no</p> <p>10 additional documents or invoices?</p> <p>11 A. Right. There's no outstanding billing or</p> <p>12 anything --</p> <p>13 Q. Yeah.</p> <p>14 A. -- like that.</p> <p>15 Q. Okay.</p> <p>16 A. Yeah. We're all caught up.</p> <p>17 Q. All right. Turning back to the reports</p> <p>18 that are in front of you as Exhibits 1 or 2, are these</p> <p>19 reports complete, as far as you're concerned?</p> <p>20 A. To the best of my knowledge, they're</p> <p>21 complete, based on what I was provided to review.</p> <p>22 Q. And do you believe what's reflected in</p> <p>23 those reports is accurate?</p> <p>24 A. I believe that my opinions are accurate.</p> <p>25 The data as presented as findings are as they are</p>	<p style="text-align: right;">Page 24</p> <p>1 A. Is it fair to say that, effectively, the</p> <p>2 opinions you're rendering here are limited to review of</p> <p>3 the geologic deposits utilized by Johnson & Johnson</p> <p>4 and -- it's kind of garbled.</p> <p>5 Q. Yeah. And Imerys.</p> <p>6 A. And to create talcum powder. So, yes, I</p> <p>7 reviewed those materials.</p> <p>8 Q. Okay. And you're not here to opine about</p> <p>9 anything outside of those geological deposits and the</p> <p>10 mining practices, et cetera, that were going on at those</p> <p>11 areas?</p> <p>12 MS. SCOTT: Objection.</p> <p>13 A. So the nature of mineralogy, as I alluded</p> <p>14 to earlier, is very systematic, right? So it's not the</p> <p>15 same deposit. It's not the same deposit, but there's</p> <p>16 Caledonia. New Caledonia is a terrain that has a lot of</p> <p>17 talc in it, that has a lot of nickel in it, and so,</p> <p>18 essentially, the geologic knowledge as a whole,</p> <p>19 essentially, I'm relying on my educational base, my</p> <p>20 research base, things like that. So being aware of the</p> <p>21 geology of talc and the mineralogy of talc, geochemistry</p> <p>22 of talc through global settings is critical to evaluate</p> <p>23 any subset of data relating to talc and associated</p> <p>24 rocks.</p> <p>25</p>
<p style="text-align: right;">Page 23</p> <p>1 interpreted by the company. So when you say -- again,</p> <p>2 I'm unexperienced.</p> <p>3 Q. Sure.</p> <p>4 A. So when you say "accurate," I don't think</p> <p>5 some of the report, some of the findings are</p> <p>6 scientifically accurate, based on the analytical</p> <p>7 methods. So...</p> <p>8 Q. Are you talking about some of your</p> <p>9 findings? I'm asking sort of what your ultimate</p> <p>10 opinions and your findings in this case. Do you believe</p> <p>11 that what you've opined to in this case is accurate in</p> <p>12 these reports?</p> <p>13 A. So is my opinion --</p> <p>14 Q. Yes.</p> <p>15 A. -- accurate?</p> <p>16 Q. Yes.</p> <p>17 A. Yes, I believe my opinion is accurate.</p> <p>18 Q. Is there anything, before we get started</p> <p>19 going through those opinions, that you want to change or</p> <p>20 amend?</p> <p>21 A. No.</p> <p>22 Q. And is it fair to say that, effectively,</p> <p>23 the opinions you're rendering here are limited to review</p> <p>24 of the geologic deposits utilized by Johnson & Johnson</p> <p>25 and Imerys to create talcum powder?</p>	<p style="text-align: right;">Page 25</p> <p>1 BY MR. FROST:</p> <p>2 Q. I'll ask it a sort of different way.</p> <p>3 I'll break it down. You didn't do any testing here of</p> <p>4 any product, right?</p> <p>5 A. I was not asked to do any testing.</p> <p>6 Q. Okay. And you're not going to render any</p> <p>7 opinions about what causes disease, anything of that</p> <p>8 nature?</p> <p>9 A. Correct. I am not a medical expert. I</p> <p>10 am not an environmental health expert.</p> <p>11 Q. And you're not going to render any</p> <p>12 opinions about what level of exposure to any particular</p> <p>13 metal or contaminate can cause disease?</p> <p>14 A. Again, I would defer for details to</p> <p>15 environmental health experts and medical experts.</p> <p>16 Q. You're not going to render any opinion</p> <p>17 that use of Johnson & Johnson talcum powder causes</p> <p>18 ovarian cancer, right?</p> <p>19 A. So I'm sorry. I am not an expert in the</p> <p>20 molecular mechanisms of carcinogenicity, if I said that</p> <p>21 correct. I don't know. I'm not a medical person. So,</p> <p>22 no.</p> <p>23 Q. All right. Looking at Exhibit 2, which</p> <p>24 is the addendum report, why did you draft this addendum?</p> <p>25 A. New materials became available.</p>

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<p style="text-align: right;">Page 26</p> <p>1 Q. When were you asked to draft the</p> <p>2 addendum?</p> <p>3 A. I think when Longo had his supplemental,</p> <p>4 and then I can't remember exactly when, but what really</p> <p>5 caught my eye was this testing where they used</p> <p>6 .1 milligrams of a sample, and that's not representative</p> <p>7 in any way, and then they use a silver membrane.</p> <p>8 Q. I'll stop you here, because we'll be here</p> <p>9 for a very long time.</p> <p>10 A. Okay.</p> <p>11 Q. So the question was: When were you asked</p> <p>12 to draft the report?</p> <p>13 A. I'm sorry. I'm sorry. You're right. I</p> <p>14 got distracted. It was in January sometime.</p> <p>15 Q. And if you look at the second paragraph</p> <p>16 of the report, it states, "After I submitted my</p> <p>17 preliminary report on November 16, 2018, I reviewed</p> <p>18 additional documents provided by Johnson & Johnson and</p> <p>19 Imerys through the course of this litigation as well as</p> <p>20 documents produced after submitting my report." Is that</p> <p>21 correct?</p> <p>22 A. Yes.</p> <p>23 Q. If you turn to pages 4 -- I'm sorry, page</p> <p>24 5 of the report. You list the supplemental materials</p> <p>25 and data considered?</p>	<p style="text-align: right;">Page 28</p> <p>1 A. I might have been confused with the Longo</p> <p>2 title. It says, "Analysis of Johnson & Johnson's</p> <p>3 historical product," so that might be the source of</p> <p>4 the...</p> <p>5 Q. Do you know if there are anything else or</p> <p>6 any other changes that you'd like to make to either the</p> <p>7 supplemental or the original report?</p> <p>8 MS. SCOTT: Objection. Asked and</p> <p>9 answered.</p> <p>10 BY MR. FROST:</p> <p>11 Q. You can answer.</p> <p>12 A. Do I --</p> <p>13 Q. Yeah. Do you know if there are any other</p> <p>14 typos or anything else you'd want to correct in either</p> <p>15 of the two reports?</p> <p>16 A. I think there are a few typos in the</p> <p>17 report, or I'm, you know, I'm not perfect so...</p> <p>18 Q. We talked about, sort of, what's in the</p> <p>19 binders over there and in the tubs. We'll start with</p> <p>20 the binders, which are the documents. Did plaintiffs'</p> <p>21 counsel provide all of the documents you relied on from</p> <p>22 both Imerys and Johnson & Johnson in this case?</p> <p>23 MS. SCOTT: Objection.</p> <p>24 A. I requested documents from the lawyers to</p> <p>25 review.</p>
<p style="text-align: right;">Page 27</p> <p>1 A. Yes.</p> <p>2 Q. Am I also correct, you only list Imerys</p> <p>3 documents as the additional materials reviewed?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. So you, in fact, did not actually</p> <p>6 review any additional Johnson & Johnson documents to</p> <p>7 create this addendum; is that correct?</p> <p>8 MS. SCOTT: Objection.</p> <p>9 A. I don't remember specifically. That may</p> <p>10 be a typo. I think I -- I think it's likely that I</p> <p>11 looked at some Johnson & Johnson documents but only</p> <p>12 ended up focusing on these others.</p> <p>13 BY MR. FROST:</p> <p>14 Q. Do you know what additional Johnson &</p> <p>15 Johnson documents --</p> <p>16 A. I don't. I don't remember.</p> <p>17 Q. Okay. And I take it because they didn't</p> <p>18 make it into the report, it's not something you're</p> <p>19 relying on?</p> <p>20 MS. SCOTT: Objection.</p> <p>21 A. I don't know.</p> <p>22 BY MR. FROST:</p> <p>23 Q. Are there any other typos --</p> <p>24 A. So I think --</p> <p>25 Q. Go ahead.</p>	<p style="text-align: right;">Page 29</p> <p>1 BY MR. FROST:</p> <p>2 Q. What did you request from the lawyers?</p> <p>3 A. I requested any documents relating to the</p> <p>4 mineralogy, the geology, things such as coring, x-ray</p> <p>5 diffraction, bulk chemical tests, electron microscopy,</p> <p>6 anything relating to, essentially, problems in</p> <p>7 manufacturing or things that are related to how well</p> <p>8 audits, for example -- audits would be a good example of</p> <p>9 something that would be a third-party objective thing,</p> <p>10 and I think there's, you know, there's an audit in here,</p> <p>11 and any, any materials that would give sort of a big,</p> <p>12 big picture of the situation at hand.</p> <p>13 Q. Did you ever ask to have access to all</p> <p>14 the documents so you could perform searches yourself?</p> <p>15 A. I don't remember. I remember I reviewed</p> <p>16 a lot of, a lot of documents, but I don't remember if I</p> <p>17 specifically asked that. I asked for things relating to</p> <p>18 what I just said.</p> <p>19 Q. Did you ever run any searches against any</p> <p>20 documents to see if there's anything additional to what</p> <p>21 was provided to you?</p> <p>22 MS. SCOTT: Object to form. You can</p> <p>23 answer.</p> <p>24 A. What do you mean by "search"? So I</p> <p>25 don't -- it was my understanding that -- so this is sort</p>

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<p>1 of a closed system that, essentially, there's the</p> <p>2 documents that the company produces. If I were to</p> <p>3 search for something else, I don't necessarily know if</p> <p>4 that's from the company, right, or that's my thought.</p> <p>5 So I did not -- I didn't do any additional searches.</p> <p>6 BY MR. FROST:</p> <p>7 Q. So you just relied on the documents as</p> <p>8 provided to you by plaintiffs' counsel?</p> <p>9 A. Yes.</p> <p>10 MS. SCOTT: Objection.</p> <p>11 A. For these, for the documents that were</p> <p>12 used.</p> <p>13 BY MR. FROST:</p> <p>14 Q. And you have no way of knowing whether or</p> <p>15 not they've given you a complete set of every document,</p> <p>16 correct, that hits the categories you asked for?</p> <p>17 MS. SCOTT: Objection.</p> <p>18 A. I think it's very representative of a</p> <p>19 set. But, I mean, as I understand, there's, you know,</p> <p>20 an enormous amount of data, as there should be, and that</p> <p>21 is -- that would be expected, but, you know, I've</p> <p>22 reviewed what was requested.</p> <p>23 BY MR. FROST:</p> <p>24 Q. You reviewed what was provided, not what</p> <p>25 was requested, correct?</p>	<p>1 There's a lot of data, as I understand it. I don't</p> <p>2 think it's reasonable to review every document.</p> <p>3 Unfortunately, I'm one person, and if there's hundreds</p> <p>4 of thousands of pages of documents, yeah, I don't think</p> <p>5 any single person can review those in a reasonable</p> <p>6 manner.</p> <p>7 BY MR. FROST:</p> <p>8 Q. So you don't think it's important, as an</p> <p>9 expert giving opinions about the overall mining and</p> <p>10 sampling and testing practices of Johnson & Johnson, to</p> <p>11 have looked at or at least had access to the complete</p> <p>12 set of documents?</p> <p>13 MS. SCOTT: Objection.</p> <p>14 A. I think it's important to have a</p> <p>15 representative set, and that representative -- you know,</p> <p>16 so -- you know, I didn't look at one document. I didn't</p> <p>17 look at a few documents. You know, here's Hopkins'</p> <p>18 deposition, for example. There's all kinds of documents</p> <p>19 in that. There's a lot. There is a lot, but it's my</p> <p>20 expert opinion that the amount of documents that I</p> <p>21 reviewed were adequate to arrive at my conclusions.</p> <p>22 BY MR. FROST:</p> <p>23 Q. And, again, that's solely based on the</p> <p>24 set of documents that was compiled for you by</p> <p>25 plaintiffs' counsel in this case given to you, which you</p>
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<p>1 A. What was provided that I requested from</p> <p>2 them.</p> <p>3 Q. And you don't know whether or not -- you</p> <p>4 have no way of telling, sitting here, whether or not</p> <p>5 you've been given the complete record, correct?</p> <p>6 MS. SCOTT: Objection. Asked and</p> <p>7 answered. You can answer if you can.</p> <p>8 A. I think it's, I think it's very</p> <p>9 representative. So I found examples where asbestos and</p> <p>10 contaminate -- essentially where asbestos was</p> <p>11 undetected. You know, I looked at a wide variety of</p> <p>12 things.</p> <p>13 BY MR. FROST:</p> <p>14 Q. But you would agree with me it's a</p> <p>15 representative set as chosen to be given to you by your</p> <p>16 counsel?</p> <p>17 MS. SCOTT: Objection.</p> <p>18 A. I think it's representative.</p> <p>19 BY MR. FROST:</p> <p>20 Q. You have no way of knowing what else</p> <p>21 might exist, correct?</p> <p>22 MS. SCOTT: Objection. Asked and</p> <p>23 answered. You can answer.</p> <p>24 A. So, yeah, there could be more bad reports</p> <p>25 out there. There could be more good reports out there.</p>	<p>1 don't know is complete or not, correct?</p> <p>2 MS. SCOTT: Objection.</p> <p>3 A. I believe it is a representative set of</p> <p>4 documents, but I did rely on what they provided as</p> <p>5 that's what I requested. I requested the documents, as</p> <p>6 I previously indicated in the answer.</p> <p>7 BY MR. FROST:</p> <p>8 Q. So you keep calling this a representative</p> <p>9 set, but how can you make a determination if a set is</p> <p>10 representative if you hadn't actually looked at or had</p> <p>11 access to the full set of documents?</p> <p>12 MS. SCOTT: Objection.</p> <p>13 A. It's my expert opinion that's a -- it's a</p> <p>14 reasonable amount of documents. There's, you know --</p> <p>15 BY MR. FROST:</p> <p>16 Q. So you're basing the representativeness</p> <p>17 off of the sheer size of the pile of documents on the</p> <p>18 table?</p> <p>19 MS. SCOTT: Objection.</p> <p>20 A. It's what I think is a representative</p> <p>21 population of documents. I mean, there's -- there are a</p> <p>22 lot of documents, but I've -- and I've looked at a lot</p> <p>23 of documents, and I've arrived at my professional</p> <p>24 opinion based on the review of those documents.</p> <p>25</p>

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<p style="text-align: right;">Page 34</p> <p>1 BY MR. FROST: 2 Q. Would it change your opinion -- 3 A. I can't ask a question, right? 4 Q. No. 5 A. Okay. All right. Yeah. 6 Q. Would it change your opinion if you knew 7 that the set of documents provided to you by plaintiffs' 8 counsel only represents a portion of the story and there 9 are hundreds and possibly thousands of additional 10 documents that weren't provided to you by counsel? 11 MS. SCOTT: Objection. 12 A. So those documents would not negate the 13 findings of the report. So, for example, if there was 14 an additional document that said talc was undetected, it 15 wouldn't negate the findings of the materials starting 16 on page 14. 17 BY MR. FROST: 18 Q. Well, that's -- I'm glad you brought that 19 up, because we'll get to those at the end of the 20 deposition, because I think you were actually not 21 provided some very important documents regarding that 22 chart, but we'll turn back to that later when we start 23 going through the report. 24 A. Okay. 25 Q. But it wouldn't change your opinion at</p>	<p style="text-align: right;">Page 36</p> <p>1 on page 5 of the shorter document. 2 Q. Okay. And these are all Longo expert 3 reports, correct, Longo testing reports? 4 A. Yes. 5 Q. Did you ever see any draft reports from 6 any other experts in these cases before you finished 7 yours? 8 A. No, I did not. 9 Q. Have you reviewed any other expert 10 reports given in any talcum powder cases other than this 11 one? You know, for example, were you provided any 12 expert reports from other cases against Johnson & 13 Johnson? 14 A. I'm trying to think about the other case 15 for a moment. I don't remember. 16 Q. And have you reviewed any deposition or 17 trial transcripts in either preparation of your report 18 or to prepare for today's deposition? 19 A. Yes. 20 Q. What depositions have you reviewed? 21 A. Hopkins. 22 Q. I guess I'll ask it a different way. 23 Other than the ones that are already reflected in your 24 report, have you reviewed any depositions of any other 25 experts in talcum powder cases, any other, you know,</p>
<p style="text-align: right;">Page 35</p> <p>1 all to know that you were only given a selection of 2 documents that supported plaintiffs' theories in this 3 case? 4 MS. SCOTT: Objection. Asked and 5 answered. 6 A. No. My opinion remains unchanged. 7 BY MR. FROST: 8 Q. And, again, it wouldn't change your 9 opinion if you knew that there are documents that 10 specifically refute some of the findings that you've 11 relied on in these reports? 12 MS. SCOTT: Objection. 13 A. Again, my opinion remains unchanged. The 14 data present demonstrates that there was asbestos 15 materials and metals materials. 16 BY MR. FROST: 17 Q. Have you reviewed any reports from other 18 experts in this case? 19 A. Yes. 20 Q. We know you reviewed Longo. You 21 mentioned that in the report. Anybody else other than 22 Dr. Longo? 23 A. Not -- let me look here. So the expert 24 reports are listed on page 97, and there are four of 25 those. And then the expert report, there's one listed</p>	<p style="text-align: right;">Page 37</p> <p>1 other than -- 2 A. Not that I remember. 3 Q. -- Dr. Downey, Dr. Hopkins? 4 A. I don't remember. 5 THE WITNESS: Can we take a little break? 6 MR. FROST: Sure. 7 VIDEOGRAPHER: We're now going off 8 record. The time is 9:53. 9 (A recess was taken from 9:53 to 10:04.) 10 VIDEOGRAPHER: We are now back on record 11 and the time is 10:04. 12 BY MR. FROST: 13 Q. All right. Before going on the break, we 14 talked about whether or not you'd read any depositions 15 of any other experts in these cases. Has plaintiffs' 16 counsel ever discussed with you the testimony of any 17 other experts in these cases? 18 MS. SCOTT: Objection. 19 MS. O'DELL: I would instruct the 20 witness -- I'm sorry. Instruct the witness not 21 to discuss anything that's been discussed or 22 communicated with plaintiffs' counsel. 23 MR. FROST: Let's mark the record. I 24 disagree with that assumption because, you know, 25 I believe any discussion of depositions in these</p>

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<p>1 cases is discoverable under the federal rules, 2 but I'll move on. All right. 3 BY MR. FROST: 4 Q. Was there anything you asked plaintiffs' 5 counsel to provide for you in this case to help prepare 6 your reports that you were not given? 7 A. I'm sorry. Can you just say that again? 8 Q. Sure. Was there anything you asked 9 plaintiffs' counsel to provide you in preparation of 10 your report that you were not given or you didn't 11 receive? 12 A. No. I believe they gave me 13 representative materials of what I requested. I'm not 14 sure, but I also have the materials that I rely on. So 15 like the, you know, reviews in mineralogy books and 16 things like that are in the reliance list, but I 17 acquired those. They did not produce those. 18 Q. Okay. That was actually my next question 19 is that the stuff that's under your reliance material 20 list, is that things that you independently found 21 yourself or that were provided to you by counsel? 22 A. Yeah, yeah. Those are things I found. 23 Q. Were any of the articles -- 24 A. Those -- 25 Q. I'm sorry?</p>	<p>1 reports or were they just provided to you and then you 2 included them in your final opinion paper? 3 A. The chart? 4 MS. SCOTT: Objection. 5 BY MR. FROST: 6 Q. That was a bad question. Did you do any 7 editing of the charts that were included in the final 8 report or did you just put them in as provided by 9 counsel? 10 A. I directed them to put them in. 11 Q. So plaintiffs' counsel ultimately put it 12 into the report the way it's structured? 13 MS. SCOTT: Objection. 14 A. I indicated the documents to be included 15 in the table, and they put it in the table. 16 BY MR. FROST: 17 Q. Is that true for all of the tables or did 18 they produce -- did they provide some of the content of 19 the tables as well? 20 MS. SCOTT: Objection. 21 A. I'd have to look to refresh. 22 BY MR. FROST: 23 Q. That's okay. Take your time. 24 A. I'm already a little tired. That table, 25 I requested them to do. And that table. Sorry. I'm</p>
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<p>1 A. Those are things I found on my own. You 2 know, many of the books I -- some I just had on my 3 shelf, you know. I've actually gone through three 4 versions of some of them. 5 Q. So were any of the reports, treatises, 6 books, et cetera, you relied on provided to you by 7 plaintiffs' counsel? 8 A. No, I don't think so. 9 Q. Did anybody help you prepare the report? 10 A. I asked counsel to create the charts that 11 are in the report, and this was my first time doing such 12 an extensive report. So I asked about organizational 13 issues, things like that. 14 Q. What about other than the charts that 15 appear in the report? Did counsel assist you with any 16 of the other -- the word just escaped my mind. I 17 apologize. 18 A. Text? 19 Q. Any of the other, sort of principle of 20 research or any of the other opinions that are in the 21 paper? 22 MS. SCOTT: Objection. 23 A. No. 24 BY MR. FROST: 25 Q. And did you have any hand at editing the</p>	<p>1 new at this, a little bit nervous. So I directed them 2 to put those tables in. 3 Q. Okay. Did you direct them to -- I'll 4 strike that. 5 So the actual documents that are 6 reflected in the tables, was that your work that you -- 7 A. Those are documents I reviewed, yes. 8 Q. Okay. And you're the one who put 9 together the list of documents for them ultimately to 10 put in table form to include in the report? 11 MS. SCOTT: Objection. Asked and 12 answered. 13 A. Ultimately, I selected the documents, 14 told them to put them in. 15 BY MR. FROST: 16 Q. In forming your opinions to this report, 17 did you have to come to any -- did you have to make any 18 assumptions that you relied on, then, for your ultimate 19 opinions? 20 MS. SCOTT: Objection. 21 A. That's kind of a tricky question. I 22 assumed that the documents provided by the company were 23 genuine. 24 BY MR. FROST: 25 Q. Okay. Any other assumptions you had to</p>

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<p>1 make to reach your opinions?</p> <p>2 A. I'm just thinking. I -- I don't think</p> <p>3 so. I -- I assume that documents that I reviewed were</p> <p>4 genuine, I guess, is maybe the best way to express that.</p> <p>5 Q. And by "genuine," do you mean, you know,</p> <p>6 part of the actual documents accompanied?</p> <p>7 A. They weren't altered in some way or --</p> <p>8 Q. Okay. Yep.</p> <p>9 A. Sometimes it was, you know, there were --</p> <p>10 so, for example, the SEM document in this report and,</p> <p>11 actually, other things, the images were extremely</p> <p>12 degraded. It appeared that several documents had been</p> <p>13 photocopied, so one could supplant things. You know,</p> <p>14 again, I don't know, so that's why I say that I assume</p> <p>15 things are genuine.</p> <p>16 Q. Okay. I think we're on the same page</p> <p>17 about what "genuine" means. I just wanted to make sure.</p> <p>18 A. Yeah.</p> <p>19 Q. All right. And do you agree with me that</p> <p>20 in forming your opinions, it's important for you to keep</p> <p>21 a fair and open mind and look at the data in an</p> <p>22 impartial way?</p> <p>23 MS. SCOTT: Objection.</p> <p>24 A. I believe it's important to look at data,</p> <p>25 yes.</p>	<p>1 role was to be objective. And I reviewed several</p> <p>2 documents, you know, numerous, numerous, numerous</p> <p>3 documents objectively.</p> <p>4 BY MR. FROST:</p> <p>5 Q. And did you know what role the counsel</p> <p>6 who engaged you had? Did you know that you were</p> <p>7 representing the plaintiffs versus the company?</p> <p>8 A. I'm sorry. I missed a word.</p> <p>9 Q. Did you know what role you were hired to</p> <p>10 do?</p> <p>11 A. I knew they were on the side of the</p> <p>12 plaintiffs, yes.</p> <p>13 Q. And you knew that, ultimately, they were</p> <p>14 looking for evidence of bad mining practices and</p> <p>15 opinions regarding inadequate sampling, things of that</p> <p>16 nature?</p> <p>17 MS. SCOTT: Objection.</p> <p>18 A. I think they -- it's my opinion that they</p> <p>19 were looking for data to support their case in some way</p> <p>20 and also evaluate, potentially, if there was not a case.</p> <p>21 BY MR. FROST:</p> <p>22 Q. Do you believe there's any additional</p> <p>23 data you need to see in order to fully evaluate the</p> <p>24 mining practices and the sampling practices by the two</p> <p>25 companies in this case?</p>
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<p>1 BY MR. FROST:</p> <p>2 Q. Do you believe it's important to look at</p> <p>3 it in an impartial way?</p> <p>4 MS. SCOTT: Objection.</p> <p>5 A. I did look at things impartially, yes.</p> <p>6 BY MR. FROST:</p> <p>7 Q. Coming in to your review of the</p> <p>8 documents, were you told what plaintiffs' liability</p> <p>9 theories were in this case?</p> <p>10 MS. SCOTT: Objection.</p> <p>11 A. I don't know what that word means.</p> <p>12 BY MR. FROST:</p> <p>13 Q. Sure.</p> <p>14 A. What's plaintiff liability theory?</p> <p>15 Q. Yeah. I'll ask it a different way.</p> <p>16 A. Okay.</p> <p>17 Q. Before you were coming in to review the</p> <p>18 documents, were you told by plaintiffs, ultimately, what</p> <p>19 an opinion or what type of opinion they were looking</p> <p>20 for?</p> <p>21 MS. SCOTT: Objection.</p> <p>22 A. No, not really. I mean, in our early</p> <p>23 discussions, my job was to evaluate the data, so -- and</p> <p>24 I feel I've done that objectively. I knew it was</p> <p>25 connected to a case involving ovarian cancer, but my</p>	<p>1 MS. SCOTT: Objection. Asked and</p> <p>2 answered multiple times.</p> <p>3 A. I would consider looking at other data,</p> <p>4 of course, but looking at that other data would not</p> <p>5 change the opinions expressed in this report. Other</p> <p>6 data doesn't negate the fact that we have all these</p> <p>7 occurrences of materials. I mean, so there's over 90</p> <p>8 occurrences documented or there's about 90 or so in the</p> <p>9 one table of asbestos. You know, it doesn't negate --</p> <p>10 for me, fundamentally, it's using the powder x-ray</p> <p>11 diffraction as the screening method that's fundamentally</p> <p>12 flawed. The reasons, you know, I don't want to -- do</p> <p>13 you want me to --</p> <p>14 BY MR. FROST:</p> <p>15 Q. We'll get to that.</p> <p>16 A. I can stop.</p> <p>17 Q. We'll turn to that later.</p> <p>18 A. Okay. All right. Good.</p> <p>19 Q. You said before you're not a medical</p> <p>20 doctor, right?</p> <p>21 A. I'm sorry? Medical doctor, no.</p> <p>22 Q. And you're not a toxicologist, right?</p> <p>23 A. Correct.</p> <p>24 Q. And do you consider yourself a regulatory</p> <p>25 expert?</p>

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<p>1 A. No.</p> <p>2 Q. And you're not an expert in regulatory</p> <p>3 processes or mine regulations?</p> <p>4 A. No, I'm not an expert.</p> <p>5 Q. Before working on this report, have you</p> <p>6 ever worked with talc before?</p> <p>7 A. In my class work, my advisor was Steve</p> <p>8 Guggenheim, and, of course, Warren Huff was my master's</p> <p>9 advisor. So I had several clay mineralogy classes, and</p> <p>10 we analyzed talc. And my Ph.D. advisor specifically,</p> <p>11 you know, he would tell me, go look at this mineral with</p> <p>12 the TEM and x-ray, so I would know and be familiar with</p> <p>13 things, so but I don't have a specific thing on talc.</p> <p>14 Q. So other than, you know, your use of it</p> <p>15 in undergraduate and graduate and Ph.D. work, you know,</p> <p>16 you've never studied talc, you've never published on</p> <p>17 talc, anything like that?</p> <p>18 A. No.</p> <p>19 Q. Other than, you know, looking at it so</p> <p>20 you'd be able to identify minerals, have you ever done</p> <p>21 any examination or testing of talc?</p> <p>22 A. Other than just looking at it for -- as</p> <p>23 far as learning the details of the mineral, no.</p> <p>24 Q. Have you ever been to a talc mine?</p> <p>25 A. Yes, in California. There's this mine in</p>	<p>1 for the record, you don't know one way or the other</p> <p>2 whether this mine --</p> <p>3 A. I don't know the exact source.</p> <p>4 MS. SCOTT: Be careful you don't talk</p> <p>5 over one another.</p> <p>6 THE WITNESS: I'm sorry.</p> <p>7 MS. SCOTT: That's okay.</p> <p>8 THE WITNESS: I apologize.</p> <p>9 BY MR. FROST:</p> <p>10 Q. And when you were at this mine in Darwin,</p> <p>11 I take it there were no mine operations continuing at</p> <p>12 the time you were visiting?</p> <p>13 A. I believe it would just be alum land.</p> <p>14 But dealings and things were -- you know, I mean, things</p> <p>15 were there.</p> <p>16 Q. And you can't tell me what type of talc</p> <p>17 that was produced, whether it was industrial talc,</p> <p>18 cosmetic talc or something else, right?</p> <p>19 A. Correct. I don't know. There's no</p> <p>20 record. We found it in a guidebook, thought it'd be a</p> <p>21 good experience for the students.</p> <p>22 Q. And other than that visit, you've</p> <p>23 certainly never been to a talc mine that is currently</p> <p>24 undergoing operation, correct?</p> <p>25 A. Correct.</p>
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<p>1 Darwin. So Darwin was this area in California on the</p> <p>2 south side of Joshua Tree, and there's asbestos all over</p> <p>3 the place, and the mine closed -- if I remember</p> <p>4 correctly, the mine closed, like, in the '50s. So it</p> <p>5 might have been, you know, the mine that was -- where</p> <p>6 things were sourced from when the Italian mines were not</p> <p>7 around or, you know, the World War II era.</p> <p>8 But, yeah, I went there with Brian</p> <p>9 Currie, and we do a field trip to Death Valley and the</p> <p>10 surrounding areas all the time. So, yes, I've been to</p> <p>11 at least that talc mine, and I've been on several --</p> <p>12 I've been on field trips to, like, metamorphic terrains</p> <p>13 in New England states, but I can't remember if I saw</p> <p>14 talc there or not. I have not physically been to the</p> <p>15 Vermont mines, but, yes, I've been to a talc mine.</p> <p>16 Q. So you just made the statement that this</p> <p>17 mine in Darwin, you know, may have been during World War</p> <p>18 II, where they -- I'm looking at the thing -- where they</p> <p>19 source talc from. That's just a guess by you, correct?</p> <p>20 A. Correct. As I said, it may have been.</p> <p>21 But the region, as I understand thinking about that</p> <p>22 field trip, you know, I may be foggy, but there's other</p> <p>23 talc mines in the area. But, yeah, there was asbestos</p> <p>24 in that.</p> <p>25 Q. Okay. But, again, I just want to clarify</p>	<p>1 Q. Have you ever published anything</p> <p>2 regarding amphiboles?</p> <p>3 A. I'm trying to think. My master's thesis</p> <p>4 had -- there were amphiboles in those bentonites. Aside</p> <p>5 from that, I don't think so, or if I did, it was not a</p> <p>6 major component. Not memorable.</p> <p>7 Q. And other than what you recall in your</p> <p>8 thesis, you've never done any testing of amphiboles or</p> <p>9 anything of that nature?</p> <p>10 A. I'm trying to -- well, I have nothing</p> <p>11 published, but I have ran across -- so I've done -- you</p> <p>12 know, I have several. I have many projects with</p> <p>13 students, and some of those projects, for example, I</p> <p>14 think I -- there were minerals that I would identify in</p> <p>15 the TEM as amphibole for the coke formation, which was</p> <p>16 kind of unusual. So the coke formation is a local</p> <p>17 bedrock.</p> <p>18 Q. Okay.</p> <p>19 A. So but nothing -- nothing in the</p> <p>20 peer-review literature, and I don't even know if it was</p> <p>21 mentioned in the abstract. I do remember occasionally</p> <p>22 running across amphiboles. It's amazing what you'll</p> <p>23 find in the TEM. There's all kind of crazy stuff if you</p> <p>24 look for it. Yeah.</p> <p>25 Q. And I think we covered this before, but</p>

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<p>1 you've never done any testing of talcum powder or 2 over-the-counter cosmetic products, right? 3 A. No. 4 Q. Before you were contacted by plaintiffs' 5 attorneys in -- it sounds like about December, give or 6 take, of 2017, had you ever done any research regarding 7 talc, talcum powder, anything of that nature? 8 A. No. 9 Q. And had you ever done any research prior 10 to being contacted about the mining practices at talc 11 mines or looking at the geological mine deposits? 12 A. I'm sorry. A research on, on talc 13 mining? 14 Q. Exactly. Talc-mining practices. 15 A. Specifically? No. 16 Q. Okay. Well, what about the geology of 17 the specific -- you know, did you ever look at the 18 specific geology of any talc mines prior to being 19 engaged in this case? 20 A. I took a metamorphic course, and during 21 my master's, under Craig Dietsch, I remember we talked 22 about talc in that class. So Craig is a metamorphic 23 petrologist. So -- and then, you know, my -- I've read 24 papers. I mean, all through my Ph.D., my advisor 25 hammered that I should read everything around the topic.</p>	<p>1 Q. And you certainly have never written any 2 opinions regarding talc, talc mining practices, you 3 know, et cetera, before getting engaged in this case and 4 the other case from Waters & Kraus, right? 5 A. Correct. 6 MS. SCOTT: Objection. 7 BY MR. FROST: 8 Q. On your CV, I know you notice you have a 9 patent for something called asbestos containment 10 composition. 11 A. Yes. 12 Q. What is that? 13 A. It's a mixture of clay minerals. 14 Q. And what's the patent? 15 A. Basically, it's a mixture of kaolinite 16 and montmorillonite, if I recall. Essentially, it's one 17 we produced but didn't really pursue. It was actually 18 my brother-in-law thought it would be a good idea. So 19 but, yeah. 20 Q. So it's patented but not in production or 21 use? 22 A. Right. And I don't regard patents as 23 peer-review literature. Those are -- that's a 24 different. 25 Q. Yeah. I actually agree with you on that</p>
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<p>1 So -- but I've not -- I haven't mapped a talc deposit, 2 for example. 3 Q. So I guess the best way to put it, and 4 you can correct me if I'm wrong, but it sounds like 5 you've read papers about talc deposits and all other 6 types of deposits. 7 A. That's in my training. 8 Q. But you never did any specific research 9 narrowing down on talc deposits, specifically? 10 A. Correct. I have no peer-review 11 literature on talc. 12 Q. Have you ever attended any conferences 13 that talk about talc mining or specific, you know, talc 14 mine geology? 15 A. I've attended several clay minerals 16 society meetings periodically throughout my career. I 17 haven't attended any in a few years. I don't remember 18 their names, but, you know, I remember seeing some stuff 19 on talc, nothing specific. I was always focused on 20 either the bentonites or palygorskite/sepiolite. 21 Q. Okay. So there might -- you know, these 22 various conferences, talc might have been a topic, but 23 it wasn't something you were there to concentrate on or 24 to talk about? 25 A. Correct.</p>	<p>1 one. 2 A. Yeah. 3 Q. I was just -- I couldn't find the 4 patents, so I was wondering what it was. 5 A. Oh, surprise. 6 Q. All right. If you want to open your 7 report to page -- it's Exhibit 1 in front of you. 8 A. Okay. 9 Q. To page 45. Do you have a summary of the 10 opinions you're rendering in this case? 11 A. Okay. 12 Q. And in looking at one through five there, 13 are those the five opinions that you believe are 14 supported by the report? 15 MS. SCOTT: Objection. 16 A. Yeah, I believe these are, these are my 17 opinions. That's the -- essentially, these are the 18 summary of those opinions. 19 BY MR. FROST: 20 Q. Okay. And these fairly reflect the 21 opinions you intend to offer in this case? There's 22 nothing else that you can think of that you're going to 23 opine about? 24 A. With respect to this report, correct. 25 Q. And then I note in the addendum report,</p>

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<p>1 there's not an additional opinion given. I think the 2 report states that it supports the opinions given in the 3 preliminary report; is that correct? 4 A. Let me look. 5 Q. That's Exhibit 2. I believe the quote is 6 that "it supports and further enhances my opinions 7 outlined in the original report"? 8 A. Correct, yeah. 9 Q. So you agree with me there are no new 10 opinions in the addendum report. It's just additional 11 support for the five opinions you plan to render in this 12 case? 13 A. There's no new opinions. The silver -- 14 there's new data, but, yeah, there's no new opinions. 15 It's the addendum supports the first. 16 Q. And I take it you haven't published this 17 report or published these opinions anywhere, have you? 18 A. Absolutely not. 19 Q. Do you intend to publish them? 20 A. No. 21 Q. Do you intend to publish any of the 22 research you've done with relation to this report? 23 A. No. 24 Q. Did anybody help you do any of the, the 25 research underlying the report?</p>	<p>1 but I had read those during my dissertation time as 2 well. 3 Q. Did you go -- 4 A. So I was -- I'm sorry. 5 Q. I'm sorry. I didn't mean to cut you off. 6 I thought you were done. 7 A. So I'm familiar with a broad range of 8 literature. 9 Q. Did you have to go out and do any 10 searches for new literature that you didn't already have 11 in your possession? 12 A. We got some materials from -- or I got 13 some materials from the library, and there were some 14 things like Gy were things I knew of and Finkelstein 15 were things I knew of that had been discussed either in 16 my classes or I ran across it previously that I had to 17 go re-get. 18 Q. Did you spend any time doing any, what 19 I'll call sort of new or independent research in 20 addition to things you've already done in the past to 21 prepare your report? 22 A. I don't understand the question. In the 23 sense that? 24 Q. For example, did you spend any time in a 25 research library trying to find all the articles about</p>
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<p>1 A. No. 2 Q. So all the opinions and all the analysis 3 in the original report and the addendum report, you 4 know, are all things that you've researched yourself and 5 are solely your opinion and your -- 6 A. Yep. 7 Q. -- based on your work. Okay. 8 So you have, I believe it's a couple 9 boxes, right, of stuff on the ground that are articles 10 and textbooks? How did you actually go about selecting 11 the literature you were going to review in this case? 12 A. The stuff outside? 13 Q. Yes, the stuff outside the documents. 14 A. So I was informed by, you know, really, 15 the core of my Ph.D. So I had a class on crystal 16 chemistry and phyllosilicates, and basically, I was 17 expected to read and learn things. And so my collection 18 of books is, in part, from that effort. And then, also, 19 I teach classes regularly, so I'm familiar with the 20 books that I use in those classes and then, also, citing 21 things for research. 22 So I had a master's student who did a 23 thesis on New Caledonia, which has talc and asbestos and 24 other things. So, essentially, you know, the Brinley 25 papers were an example of, you know, those came back up,</p>	<p>1 the different geological deposits at issue in this case? 2 A. No. My opinion, the knowledge set I had 3 generated over decades was appropriate reference point. 4 So I didn't, I didn't look at, you know, French 5 literature, Chinese or Russian literature, for example. 6 Q. Do you agree with me that the standard 7 for rendering your opinions in peer-reviewed literature 8 is different than the standard for rendering opinions in 9 litigation cases? 10 MS. SCOTT: Objection. 11 A. That's a -- sort of a complex question. 12 Can I talk about? 13 BY MS. SCOTT: 14 Q. Sure. 15 A. So industrial mineral companies, margins 16 are not great. So, basically, the profits are not 17 great. So, you know, there's not -- well, I should back 18 up. Industrial mineral companies, other mineral 19 companies, they rely on peer-review literature for their 20 analytical standards and practices. So, essentially, 21 peer-review literature is kind of part of that. They 22 don't -- mineral companies don't necessarily talk to 23 each other. There are, like, societies, so there's a 24 clay mineral society. I think there's a zeolite 25 society. But the sort of industrial secrets or the</p>

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<p style="text-align: right;">Page 58</p> <p>1 details and methods, you know, everyone's afraid that 2 they're going to get ripped off from someone else. So 3 peer-review literature is a sort of common ground that 4 everyone uses. 5 Q. I guess I'll ask the question a different 6 way. 7 A. Okay. 8 Q. Because it was about, sort of, the 9 standard for opinions. Do you believe that the standard 10 of review for an opinion, you know, such as in the 11 expert report you've given in this case, is the same or 12 different than the standard review if you were trying to 13 publish a peer-reviewed article on the same subject? 14 MS. SCOTT: I'm going to object and ask 15 him not to speculate on your initial question in 16 any legal standards. 17 A. Yeah. I am -- as I -- I'm not familiar 18 with legal review. 19 BY MS. SCOTT: 20 Q. Do you believe the -- when you were 21 writing the report, do you believe that the opinions in 22 this report, you know, would meet or be sufficient for 23 peer-review publication? 24 MS. SCOTT: Objection. 25 A. I don't want -- I'm not an editor. I</p>	<p style="text-align: right;">Page 60</p> <p>1 regarded that metamorphic rock, metamorphic terrains 2 take a long time to form. So pressure temperature 3 loops, and this is well documented in the geologic 4 literature. You know, it's in the classwork that I've 5 had. 6 Q. Would you agree with me that some talc 7 deposits form -- you know, the formation of talc 8 deposits, some take a lot longer, some take a lot 9 shorter, depending upon the characteristics of the 10 formation? 11 MS. SCOTT: Objection. 12 A. I'm not gonna speculate without data. 13 But, you know, generally it's accepted that talc 14 deposits take several millions of years to form. 15 BY MR. FROST: 16 Q. What's your basis of that opinion? 17 A. My classwork. 18 Q. Can you tell me what factors affect the 19 formation of talc, what the controlling factors of 20 metamorphism would be? 21 A. Heat and pressure and fluids. 22 Q. Would you agree with me that not all talc 23 is formed with the exact same amount of heat, pressure 24 and fluids in the mix? 25 A. There is variability.</p>
<p style="text-align: right;">Page 59</p> <p>1 don't want to speculate. 2 BY MS. SCOTT: 3 Q. That's fine. Turning in to your report. 4 Start at page 2. So you state that "Talc is a mineral 5 derived almost exclusively from metamorphic deposits," 6 right? 7 A. Correct. 8 Q. You also agree with me that not all talc 9 forms through a metamorphic process, right? 10 A. You can have soils developed on talc 11 deposits, so, yes. 12 Q. Yes, you can have talc form -- 13 A. Developed on. And then you can also have 14 potential hydrothermal alteration at mid-ocean ridges, 15 which is also a metamorphic. It's hydrothermal 16 alteration. 17 Q. You also state further down that the 18 process of metamorphism occurs over several tens of 19 millions of years. Is that always the case? 20 A. Generally, that's the case, you know, in 21 rocks where you have talc occurring, yes. 22 Q. Do you think that's true for all talc 23 deposits that have formed? 24 A. For, you know, the instances of mid-ocean 25 ridge, perhaps not, but, essentially, it's generally</p>	<p style="text-align: right;">Page 61</p> <p>1 Q. Would you agree with me that not all talc 2 deposits are geologically the same? 3 MS. SCOTT: Objection. 4 A. I don't think any -- every rock and every 5 geologic deposit has its own history, so one of the big 6 things that's come out in mineralogy is mineralogical 7 evolution. And Bob Hazen's paper talks about this, and 8 there's been several successive papers. So based on 9 that, you know, every deposit has individual 10 characteristics, but there's general sort of groups or 11 classes. 12 BY MR. FROST: 13 Q. And you'd agree with me that not every 14 mined deposit of talc is the same either, correct? 15 A. It all depends on what you mean by "the 16 same." You know, you can have things that are not the 17 same but very similar. 18 Q. Sure. But not every mined deposit is 19 going to be exactly the same chemically, geologically. 20 They're all going to form in different ways at different 21 times. Would you agree with that? 22 A. Unless they are geologically related. So 23 you can have two parts. You can have multiple deposits 24 in the same geologic terrain that form at approximately 25 the same time. Other issues, I mean there's issues with</p>

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<p style="text-align: right;">Page 62</p> <p>1 geochronology, right? So, you know, age range errors 2 can be plus or minus 10 million years. So if you have a 3 age of a metamorphic deposit that is talc and the age is 4 plus or minus 20 million years, you know, based on the 5 available data, that's a reasonable, you know, 6 chronometric value. 7 Q. Sure. And based upon when it formed, how 8 it formed, the pressures, the temperatures, whether or 9 not there's variability of that would effect what other 10 minerals might be with the talc, right? 11 A. Correct. 12 Q. And also depending what surrounding rock 13 there is to the rock that changed to talc would also, 14 you know, affect what might be on the margins of a talc 15 deposit, for example? 16 A. I'm sorry. The last part of your 17 question? 18 Q. Sure. So depending what the surrounding 19 rock was to the rock that metamorphosed to talc would 20 also affect what you would see in the black wall, for 21 example, what you see at the boundaries for the talc, 22 right? 23 A. It can, if there's a reaction or not, so 24 it's dependent upon the situation. 25 Q. That's what I was going to stay. It's</p>	<p style="text-align: right;">Page 64</p> <p>1 A. Yes, it does. 2 Q. And that's effectively what we're talking 3 about here, is that it's the other minerals that were 4 around during the formation of the talc. They may be in 5 the deposit, they may not, and they may be different 6 depending on deposits, right? 7 MS. SCOTT: Objection. 8 A. I'm sorry. Can you -- 9 BY MS. SCOTT: 10 Q. Sure. So you agree with me that not 11 every talc deposit is going to have the same exact 12 associated other minerals with talc, right? 13 MS. SCOTT: Objection. 14 A. It depends, because, I mean, you have -- 15 so, in mineralogy, we have a term called "perigenesis." 16 So essentially, there are -- these common minerals are 17 associated with each other. So out of context, for 18 example, galena and sphalerite are very commonly 19 associated with each other. 20 So, essentially, I think a more correct 21 way of saying things is that chrysotile asbestos and 22 talc are commonly associated with each other. So 23 perhaps not all talc deposits have the same mineral 24 assemblage, but many of them do have very similar 25 mineral assemblages, and that's even when the chemistry</p>
<p style="text-align: right;">Page 63</p> <p>1 variable, and it changes from deposit to deposit? You 2 have to look specifically? 3 A. That's why every deposit should be 4 evaluated with an appropriate core density and high 5 sampling density. 6 Q. So in order to fully understand what's in 7 a particular talc deposit, you really do need to know 8 how it formed, what was with it when it formed, what's 9 around it, things like that, right? 10 A. I'm sorry. To understand a talc deposit? 11 Q. Yes. 12 A. At what level or what understanding, what 13 context? 14 Q. To understand what specifically, you 15 know, is associated with that talc, what other minerals 16 might be associated with the talc, you really have to 17 look at the specific deposit, how it was formed, what 18 other constituent minerals were around it, things of 19 that nature, correct? 20 A. Yes. One should evaluate what is in the 21 deposit and what is adjacent to the deposit. 22 Q. You also state on page 2, on the next 23 paragraph down, that "Talc can have, and commonly does 24 have, natural impurities." And that's effectively what 25 we're talking about?</p>	<p style="text-align: right;">Page 65</p> <p>1 varies. 2 BY MS. SCOTT: 3 Q. And that's what I'm getting to, is just 4 because some minerals are associated with talc doesn't 5 mean that other mineral is going to be in every single 6 talc deposit in the world, right? 7 MS. SCOTT: Objection. 8 A. Correct, but that doesn't mean that's not 9 very common, either. 10 BY MR. FROST: 11 Q. Sure. But we're talking about -- you 12 agree with my statement that not every single talc 13 deposit in the world will have all of the same exact 14 accessory minerals associated with it, right? 15 MS. SCOTT: Objection. Calls for 16 speculation. 17 A. Yeah. I don't want to speculate on that. 18 BY MR. FROST: 19 Q. It's not speculation. 20 A. Because, you know, there's -- 21 Q. Isn't it science? 22 A. You know, I go back to the New Caledonia 23 example. It has talc, but not every talc deposit has 24 New Caledonia assemblages. 25 Q. Okay. So the answer to my question would</p>

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<p>1 be yes, right, that not every single talc deposit has 2 the exact same accessory minerals associated with it? 3 MS. SCOTT: Objection. 4 A. Correct. 5 BY MR. FROST: 6 Q. And you also agree with me that -- I'm 7 going to use the word, you know, "pure," to mean more 8 talc, but there are some talc deposits that are more 9 pure than other talc deposits. There's some talc 10 deposits that are comprised of more talc than others, 11 correct? 12 MS. SCOTT: Objection. 13 A. It's -- so it's speculative. I don't 14 know exactly what you mean by "pure." So it's been 15 known, for example, that at the atomic level, you can 16 have intergrowths with chrysotile with talc. So, yeah. 17 I'm really not quite sure how to answer that question. 18 BY MR. FROST: 19 Q. So you have no opinion that if I were to 20 go find a talc deposit over here and find one over here, 21 that one might have -- be comprised of more talc or have 22 a more pure metamorphism of the talc than another? 23 MS. SCOTT: Objection. 24 A. Without any priority knowledge -- yeah. 25 I would want to -- to answer that question correctly,</p>	<p>1 chrysotile. 2 BY MR. FROST: 3 Q. So as an expert in geology, you can't 4 tell me as a fact, sitting here today, that there are 5 some talc deposits that are exist in the world that are 6 comprised of more talc than others? 7 MS. SCOTT: Objection. Asked and 8 answered. 9 A. I think I answered that, yeah. There's 10 some that have a higher percentage of talc, but there's 11 impurities that also occur. So, you know, if you have 12 10 percent asbestos in one mine and 2 percent asbestos 13 in one and 30 percent in another, so, yes, that's, 14 that's possible. 15 BY MR. FROST: 16 Q. I don't think you're understanding my 17 question. More fundamentally, don't you agree with me 18 some talc deposits are only made up of 20 percent talc 19 and are predominantly other minerals, as were other talc 20 deposits are made up of, for example, 50 or 60 percent 21 talc? 22 A. So I'm unclear. Are you talking about 23 talc deposits or talc ores? 24 Q. I'm talking about talc deposits, 25 generally, geological formations of talc.</p>
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<p>1 you need to analyze each individual deposit. 2 BY MR. FROST: 3 Q. As an expert in geology, you can't tell 4 me that there are some deposits of talc in the world 5 that are more pure than others, that are more comprised 6 of talc than others? 7 MS. SCOTT: Objection. 8 A. One would expect -- you know, so 9 materials are variable in percentages, but I don't think 10 it's reasonable just to declare -- I mean, it seems like 11 a -- perhaps I'm misinterpreting it, but it seems like a 12 arbitrary setup or question. So the -- one cannot -- 13 what I'm trying to say is one cannot predict the exact 14 impurities in any given deposit. 15 There are general -- using the 16 peer-reviewed literature and well documented, you know, 17 work of archives going back, for example, Hess, 1933, 18 you know, it is common and reasonable to know that 19 there's some, or very, very likely, asbestos materials 20 are associated with talc. 21 And so it is reasonable that -- it's a 22 reasonable, scientifically reasonable interpretation 23 that one would expect impurities of many types, but they 24 may not be the same. So we have examples where there's 25 tremolite, and there's examples where there's</p>	<p>1 A. So, yeah. Talc can occur at a variable 2 concentration in metamorphic rocks. 3 Q. You will also agree with me that some 4 talc deposits can be larger than others, right, 5 geologically? 6 A. Yes. 7 Q. You'll agree with me that talc is sort of 8 all over the place and what are the mine deposits are 9 sort of unique? 10 A. No. Talc is not all over the place. 11 Metamorphic rocks comprise approximately 10 percent or 12 so of rocks exposed at the surface of the earth, and so 13 talc, by that definition alone, talc is not all over the 14 place. 15 Q. You'd agree with me talc can be found 16 from Quebec to Georgia, for example? 17 A. I think that's a very general in, perhaps 18 in consumers' homes, in baby powder bottles. The -- 19 Q. You don't think there are talc formations 20 found in the Appalachian Mountains from Quebec through 21 Georgia? 22 A. There -- 23 MS. SCOTT: Objection. 24 A. There are other talc deposits in North 25 America, yes. They're not restricted to Vermont, but</p>

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<p>1 talc deposits do occur.</p> <p>2 BY MR. FROST:</p> <p>3 Q. And talc deposits occur in places like</p> <p>4 Alabama, Texas, Minnesota, California? You'll agree</p> <p>5 with me on that as well, right?</p> <p>6 A. I remember some of the specifics in the</p> <p>7 Southern states. I know they occur in California.</p> <p>8 Q. Will you agree with me that some talc</p> <p>9 deposits are larger than others?</p> <p>10 MS. SCOTT: Objection.</p> <p>11 A. Yes. You can have small talc deposits.</p> <p>12 You can have big talc deposits. You can have -- they're</p> <p>13 just like granites. You can have small granites and</p> <p>14 large granites. You can have -- you know, a variation</p> <p>15 in size and scale and complexity is a very common trait</p> <p>16 in geologic terrains.</p> <p>17 BY MR. FROST:</p> <p>18 Q. You'd agree with me because of variations</p> <p>19 in size, scale, complexity, accessory minerals, et</p> <p>20 cetera, you can't make general statements about talc</p> <p>21 deposits. Not every talc deposit's the same, right?</p> <p>22 MS. SCOTT: Objection.</p> <p>23 A. To some level, I think one can. You can</p> <p>24 make general statements about rock types, what is common</p> <p>25 or likely to occur. If we were able to precisely</p>	<p>1 but you can have minerals that have fibrous habits that</p> <p>2 are not microscopic.</p> <p>3 So an example would be millerite, which</p> <p>4 is a nickel sulfide that, essentially, you have these</p> <p>5 very long black fibers, and it's very commonly -- that's</p> <p>6 what it occurs as. And the fiber -- fibrous textures,</p> <p>7 you know, essentially, all morphologies are driven by</p> <p>8 the unit cell and, essentially, bonding strengths and</p> <p>9 defect densities and things like that. So fibers are</p> <p>10 common in asbestiform materials.</p> <p>11 Q. Is a fibrous habit different than the</p> <p>12 asbestiform habit?</p> <p>13 A. So a fiber would be more of a subset of</p> <p>14 asbestiform. So if I had a chunk of chrysotile, that</p> <p>15 would be asbestiform, and it would be composed of</p> <p>16 fibers.</p> <p>17 Q. So fibers are a smaller subset of</p> <p>18 asbestiform?</p> <p>19 A. Generally.</p> <p>20 Q. Can you define for me what "asbestiform</p> <p>21 habit" means? Are you able to define what "asbestiform</p> <p>22 habit" means without referencing your report?</p> <p>23 A. Asbestiform basically is --</p> <p>24 Q. Here, could we do it this way? Without</p> <p>25 looking at your report, can you define for me what</p>
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<p>1 predict just by thought the distribution of ore, we</p> <p>2 would have no problem finding platinum and gold and</p> <p>3 those kinds of things, right? So does that answer the</p> <p>4 question?</p> <p>5 Q. Sure.</p> <p>6 THE WITNESS: Can we take a break?</p> <p>7 MR. FROST: Sure.</p> <p>8 VIDEOGRAPHER: We are now going off</p> <p>9 record, and the time is 10:48.</p> <p>10 (A recess was taken from 10:48 to 11:03.)</p> <p>11 VIDEOGRAPHER: We are now back on record,</p> <p>12 and the time is 11:03.</p> <p>13 BY MR. FROST:</p> <p>14 Q. Would you describe for me what a "fibrous</p> <p>15 habit" means?</p> <p>16 A. In general, it is an elongated particle</p> <p>17 that -- and the -- so on page 4, I indicate there's</p> <p>18 length or width ratios for fibers which have fibrous</p> <p>19 habit of three to one, and then NIOSH is five to one.</p> <p>20 BY MR. FROST:</p> <p>21 Q. Okay. Can you define for me what a</p> <p>22 "fibrous habit" means? Does it purely mean dimensions</p> <p>23 of three to one to five to one?</p> <p>24 A. So in the general context of mineralogy,</p> <p>25 fiber can -- it's actually a little bit of a loose term,</p>	<p>1 "asbestiform" means?</p> <p>2 MS. SCOTT: Objection. If he needs to</p> <p>3 look at his report, he can look at his report.</p> <p>4 MR. FROST: Well, I just want to see if</p> <p>5 he can do it without looking at the report.</p> <p>6 BY MR. FROST:</p> <p>7 Q. But if you need to look at your report,</p> <p>8 just let me know that you have to look at your report to</p> <p>9 define it.</p> <p>10 MS. SCOTT: Objection.</p> <p>11 A. Asbestiform essentially is a texture that</p> <p>12 is -- the particles are elongated. They have a high</p> <p>13 general aspect ratio.</p> <p>14 BY MR. FROST:</p> <p>15 Q. So asbestiform is purely a texture?</p> <p>16 MS. O'DELL: Object to the form.</p> <p>17 A. A texture with respect to what?</p> <p>18 BY MR. FROST:</p> <p>19 Q. Well, that's what you just said. That's</p> <p>20 what I'm trying to figure out. You used the word</p> <p>21 "texture." You defined asbestiform as a texture?</p> <p>22 A. So texture is a general term that means</p> <p>23 the size, shape and distribution of mineral particles.</p> <p>24 Q. Is that different than the morphology?</p> <p>25 A. Morphology generally refers to a crystal</p>

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<p style="text-align: right;">Page 74</p> <p>1 or single phase.</p> <p>2 Q. What do you mean by that, the "single</p> <p>3 phase"?</p> <p>4 A. Single phase, phase is like a -- phase is</p> <p>5 a thermodynamic term. So, in theory, it is something</p> <p>6 that is separable from a system. So you can have</p> <p>7 something like chrysocolla that is grown around and fill</p> <p>8 some other mineral, where you can have glass. Glass is</p> <p>9 a separate phase. Or it can also be a mineral, so it's</p> <p>10 more of just a thermodynamic term.</p> <p>11 Q. Do you agree with me that in order for a</p> <p>12 mineral to be asbestiform, it has to grow in an</p> <p>13 asbestiform habit?</p> <p>14 MS. SCOTT: Objection.</p> <p>15 A. No. So talc is mechanically soft, and I</p> <p>16 can certainly imagine scenarios where you have</p> <p>17 tremolite, large tremolite crystals that exist in a talc</p> <p>18 schist, and that talc schist then experiences continued</p> <p>19 dynamic metamorphism, so things move, and that talc</p> <p>20 crystal can be -- other talc -- or, I'm sorry, the</p> <p>21 tremolite crystal in the talc can then hit other talc or</p> <p>22 other tremolite crystals and essentially abrade and</p> <p>23 grind and be broken down into smaller elongate, elongate</p> <p>24 mineral particles which would be fibrous, and that would</p> <p>25 be one way of producing that texture.</p>	<p style="text-align: right;">Page 76</p> <p>1 BY MR. FROST:</p> <p>2 Q. If you look at page 4 of your report,</p> <p>3 second paragraph, under "Asbestos," you write that</p> <p>4 "Asbestiform refers to a mineral that has grown into a</p> <p>5 fibrous aggregate of long, thin flexible crystals that</p> <p>6 readily separate into smaller crystals of a" smaller</p> <p>7 "length-to-width aspect ratio." You agree with me</p> <p>8 that's very different than what you just told me, right?</p> <p>9 MS. SCOTT: Objection. You just misread</p> <p>10 something. It says, "smaller crystals of a</p> <p>11 similar length."</p> <p>12 MR. FROST: Oh, I apologize.</p> <p>13 MS. SCOTT: No problem.</p> <p>14 A. So I think that's a correct statement.</p> <p>15 BY MR. FROST:</p> <p>16 Q. Which one, the one in your report or the</p> <p>17 one you just gave me?</p> <p>18 MS. SCOTT: Objection.</p> <p>19 A. Both.</p> <p>20 BY MR. FROST:</p> <p>21 Q. You think you can, a mineral can both</p> <p>22 grow as you have here in a fibrous aggregate of long or</p> <p>23 you can create it?</p> <p>24 A. It can -- it can result from the process.</p> <p>25 So in the broad context, if you are crushing or milling</p>
<p style="text-align: right;">Page 75</p> <p>1 BY MR. FROST:</p> <p>2 Q. Is that different than growing in an</p> <p>3 asbestiform habit? In order to be asbestiform, do you</p> <p>4 have to grow in the asbestiform habit?</p> <p>5 MS. SCOTT: Objection.</p> <p>6 A. There's not necessarily -- mineral growth</p> <p>7 would not necessarily be a part of that.</p> <p>8 BY MR. FROST:</p> <p>9 Q. So mineral growth has nothing to do with</p> <p>10 whether or not a mineral is asbestiform?</p> <p>11 MS. SCOTT: Objection.</p> <p>12 A. I think there's a false dilemma. You</p> <p>13 know, as I described, so you can have that, you know, a</p> <p>14 nice, happy actinolite or tremolite crystal. Stress is</p> <p>15 applied during metamorphism and that then breaks apart</p> <p>16 and you can end up with material that is -- that meets</p> <p>17 the definition of a fiber.</p> <p>18 BY MR. FROST:</p> <p>19 Q. So as far as you're concerned, all fibers</p> <p>20 are asbestiform?</p> <p>21 MS. SCOTT: Objection.</p> <p>22 A. No. My mineral, one of the minerals I'm</p> <p>23 an expert in, palygorskite/sepiolite, often the</p> <p>24 individual crystals are referred to as fibers.</p> <p>25</p>	<p style="text-align: right;">Page 77</p> <p>1 a talc ore and there's tremolite in it, basically, you</p> <p>2 can process that, it's my expert opinion, that you can</p> <p>3 process that and result in producing asbestiform</p> <p>4 materials or fibers, elongated mineral particles.</p> <p>5 Q. So are all elongated mineral particles</p> <p>6 asbestiform?</p> <p>7 A. I'm sorry. I misspoke. Not necessarily,</p> <p>8 no.</p> <p>9 Q. Okay. Why don't we look at -- well,</p> <p>10 first off, do you have any studies or research that you</p> <p>11 rely on to support your opinion that you can change</p> <p>12 something that grew prismatic into something that's now</p> <p>13 asbestiform?</p> <p>14 A. So I think it's reasonable, based on my</p> <p>15 knowledge of crystal chemistry.</p> <p>16 Q. You can't point me to a single</p> <p>17 peer-reviewed study or NIOSH or anything else that has</p> <p>18 ever supported this opinion?</p> <p>19 MS. SCOTT: Objection.</p> <p>20 A. So I was taught by Steve Guggenheim that</p> <p>21 you can reduce particle size, and when you reduce</p> <p>22 particle size in minerals, essentially, that is driven</p> <p>23 by cleavage. So basically every mineral has a unit</p> <p>24 cell, and that is definition of the elements that are</p> <p>25 unique to that mineral and a specific arrangement.</p>

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<p style="text-align: right;">Page 78</p> <p>1 And, essentially, the nature of bonds in 2 that mineral will be weaker along certain planes for 3 certain minerals such as amphiboles. So basically what 4 happens is when you apply stress, it doesn't matter if 5 that is a five-foot piece of tremolite or if it is a 6 micron piece of tremolite. Essentially, it's absolutely 7 reasonable that if you apply stress and you break that, 8 it will break into smaller pieces, and you can end up 9 with -- essentially, the hat or the shape is the same. 10 Or, essentially, hat or shape is driven by those 11 crystallographic parameters. 12 BY MR. FROST: 13 Q. All right. Do you know what a cleavage 14 fragment is? 15 A. Yeah. It's essentially a fragment that 16 has broken off. 17 Q. And you're telling me that cleavage 18 fragments can be asbestiform that have broken off as 19 prismatic crystals? 20 A. I think they can, so they can. They can 21 meet the crystallographic requirements. 22 Q. Is your opinion generally accepted by the 23 scientific community? 24 A. I have not presented or published on 25 that, but I think, based on my experience and what I</p>	<p style="text-align: right;">Page 80</p> <p>1 particular particle is asbestiform or a cleavage 2 fragment, and your answer to that was cleavage fragments 3 implies that through some mechanism process, it's been 4 developed. That's what I'm asking. What is this 5 mechanism process? Is this an outside force? Are you 6 talking about processing -- 7 A. Mechanical. 8 Q. You're talking about mechanics. So if a 9 fragment cleaves off because a mechanical force is 10 applied to it, it's a cleavage fragment? If it occurs, 11 if it naturally cleaves, then it's asbestiform? 12 MS. SCOTT: Objection. 13 A. You can have, as I mentioned before, you 14 can have the situations totally reasonable, both in the 15 processing and then the natural geologic process, where 16 you can have a tremolite crystal, for example, that 17 essentially is deformed through metamorphic processes. 18 You can have multiple directions of force, and so, 19 basically, you can end up with particles that are 20 asbestiform as a result of that, and then you can grind, 21 crush, process things that also have an asbestiform 22 texture. 23 BY MR. FROST: 24 Q. Are there any standards you're relying on 25 to make this determination of asbestiform versus</p>
<p style="text-align: right;">Page 79</p> <p>1 know about crystal chemistry of minerals, that is a 2 reasonable interpretation. 3 Q. Okay. So your interpretation is that a 4 particle can become asbestiform, even if it didn't form 5 naturally in an asbestiform habit by this cleaving down 6 to a particular particle size? Is that a fair summary? 7 MS. O'DELL: Object to the form. 8 A. You, through processing, you can modify 9 many things. 10 BY MR. FROST: 11 Q. So can you tell me what particular 12 properties will determine whether or not a particle was 13 a cleavage fragment versus an asbestiform fragment? 14 MS. SCOTT: Objection. 15 A. Cleavage fragment implies that it has, 16 through some mechanical process, it's been developed. 17 BY MR. FROST: 18 Q. So a cleavage fragment purely refers to 19 some outside mechanical process? 20 MS. SCOTT: Objection. 21 A. What do you mean by "purely"? 22 BY MR. FROST: 23 Q. That's what I'm trying to figure out, 24 what your definition is. So I asked you, you know, what 25 the properties are that will determine whether or not a</p>	<p style="text-align: right;">Page 81</p> <p>1 cleavage fragment? 2 MS. SCOTT: Objection. 3 A. I'm using the terminology as described in 4 my mineralogy class that I took from Dr. John Grover in 5 1991, and he -- he grew some of the artificial, 6 synthetic fibers for the rat tests in the '70s. 7 BY MR. FROST: 8 Q. Okay. Other than this class you had with 9 Dr. John Grover, you can't name me another source, 10 another peer-reviewed literature, a scientific paper 11 that supports your theory? 12 MS. SCOTT: Objection to form. 13 MR. LAPINSKI: I was going to say, make 14 sure you let him ask the full question before 15 you start to answer. 16 THE WITNESS: Okay. I'm sorry. 17 BY MR. FROST: 18 Q. Do you want me to reask it? 19 A. The terms were used in my graduate school 20 classes as well. I think that -- yeah. 21 Q. And your opinion is whether or not this 22 fragment that breaks off, whether or not it's 23 asbestiform or cleavage doesn't have anything to do with 24 the way in which the particle originally formed? 25 MS. SCOTT: Objection.</p>

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<p>1 A. So crystallographically, in a way, the 2 term's not necessarily extremely relevant. It is the 3 physicality of a particle is such that, you know, it's 4 driven by, essentially, the science. So you can crush, 5 you can grind something, and you can end up with an 6 asbestiform particle. 7 MR. FROST: Let me look at some articles. 8 I'm going to mark this as -- I believe, we're at 9 Exhibit 3. 10 (Exhibit 3 was marked for 11 identification.) 12 BY MR. FROST: 13 Q. Do you recognize this paper? 14 A. No, I do not. I have not seen this 15 report. 16 Q. This is not the IRSST 2010 Montreal paper 17 you reference in your report? 18 A. I don't remember. 19 Q. Look at your -- let me see. I want to 20 find a place that you reference this. If you look at 21 Footnote 5 on page 4. 22 A. I don't see a Footnote 5 on page 4. 23 Q. Of your report. 24 MS. SCOTT: Of your report. 25 A. Oh, I'm sorry. Okay. Yeah.</p>	<p>1 high aspect ratio, (length/diameter ratio), increased 2 mechanical properties, flexibility and durability. 3 "In the asbestiform morphology, the 4 crystals grew by forming long and filiform fibers. 5 These fibers are found in bundles that can easily 6 separate into smaller fibers (fibrals), which, during 7 processes, retain their surface and activity properties. 8 "OSHA (1992) specifies that the 9 asbestiform criterion does not depend on the crystalline 10 structure but on how the crystal grows or its 11 crystalline formation. When pressure is applied to" an 12 asbestiform "fiber, it will bend rather than break." 13 Did I read that correctly? 14 MS. SCOTT: With one correction. 15 MR. FROST: I did miss one? 16 MS. SCOTT: Asbestos fiber, not 17 asbestiform fiber. 18 MR. FROST: Oh, I apologize. 19 BY MR. FROST: 20 Q. Did I read that -- other than that, did I 21 read this correctly? 22 A. Okay. Yeah. 23 Q. Do you agree with me this definition is 24 very different than the definition you've given me? 25 MS. SCOTT: Objection.</p>
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<p>1 BY MR. FROST: 2 Q. Do you agree that this is the same report 3 that you have referenced in Footnote 5 on your paper? 4 A. Yeah. 5 Q. Have you ever read this report before? 6 A. I think so. 7 Q. And this is something -- 8 A. I'm tired. 9 Q. And this is something you rely on 10 otherwise in your paper, correct? 11 A. I forget the specifics of where I've 12 cited it. 13 Q. If you turn to page 10, please. 14 MS. SCOTT: Of the report or of the -- 15 MR. FROST: Of the paper, the IRSST 16 paper. 17 A. Page 10. 18 BY MR. FROST: 19 Q. So it's Section 5.1.2, "Asbestiform." 20 A. Okay. 21 Q. It states, "The term 'asbestiform; refers 22 to a morphology originating from the natural 23 crystallization of a mineral into small crystals, into 24 hair-like fibers (unidimensional). This morphology 25 gives the mineral-specific characteristics, including a</p>	<p>1 A. Not necessarily. It is more specific, 2 but it's, you know, generally in line. 3 BY MR. FROST: 4 Q. Generally in line. Doesn't the IRSST 5 paper specifically state that an asbestiform crystal has 6 to grow into that structure to be asbestiform? 7 A. It says that, but again -- 8 Q. You disagree with that? 9 MS. SCOTT: Objection. 10 A. It -- 11 BY MR. FROST: 12 Q. It's okay. You can disagree with it. 13 A. In my -- it's permissive, not exclusive. 14 So I - I -- 15 Q. I don't -- where does it say it's 16 permissive, not exclusive? Is that in this paper? 17 A. No. My class terminology might not be 18 consistent with this. 19 Q. Okay. Let's look at another one. What 20 exhibit are we on? Four? I would like to mark this as 21 Exhibit 4. I'll give you a copy. 22 MR. FROST: Are we not on four? 23 MS. SCOTT: I think it's five. 24 MR. FROST: Are we on five? I thought we 25 were on five, too.</p>

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<p>1 MS. SCOTT: I think we're on five.</p> <p>2 MR. FROST: Okay. Yeah. I was going to</p> <p>3 say maybe we can keep track.</p> <p>4 VIDEOGRAPHER: I'm keeping track, but the</p> <p>5 last one you just gave him, you said three.</p> <p>6 MR. FROST: Oh, okay. So I guess we are</p> <p>7 on 4. We'll mark this whatever the next exhibit</p> <p>8 is.</p> <p>9 (Exhibit 4 was marked for</p> <p>10 identification.)</p> <p>11 BY MR. FROST:</p> <p>12 Q. Take a look at it. Have you ever seen</p> <p>13 this paper before?</p> <p>14 A. I'm not sure. I immediately don't see it</p> <p>15 in the reference list.</p> <p>16 Q. I can tell you, it's not on your</p> <p>17 reference list.</p> <p>18 A. Okay. Yeah. I have not seen this</p> <p>19 before.</p> <p>20 Q. Have you ever heard of Dr. William J.</p> <p>21 Campbell?</p> <p>22 A. No, I have not.</p> <p>23 Q. You'd agree with me that this is a report</p> <p>24 from the United States Department of the Interior,</p> <p>25 Bureau of Mines?</p>	<p>1 that are related to the crystal structure and are always</p> <p>2 parallel to crystal faces." That's in line with what</p> <p>3 you've described, right, for cleaving?</p> <p>4 A. That statement is not correct.</p> <p>5 Q. It's not correct?</p> <p>6 A. You can have cleavage that is, has a</p> <p>7 variety of degree as a perfection to it.</p> <p>8 Q. And, again, do you have -- can you cite</p> <p>9 me a study that you're relying on for that opinion?</p> <p>10 A. I can probably point to a book, but it's</p> <p>11 something that is -- I mean, it's taught in mineralogy,</p> <p>12 introduction to mineralogy. You have different levels</p> <p>13 of perfection of cleavage. So, for example, micas are</p> <p>14 said to be perfect in cleavage, and a lot of the</p> <p>15 amphiboles are said to be good but not necessarily</p> <p>16 perfect.</p> <p>17 And, actually, you can see in this SEM</p> <p>18 image, there's all kinds of irregularities on the</p> <p>19 surface. And on this particular SEM image, it's</p> <p>20 extremely bright. The contrast is wrong. It's not --</p> <p>21 you know, you can't tell what is on that right end of</p> <p>22 the image that is the tremolite particle there.</p> <p>23 Q. I'll stop you here. I'm confused because</p> <p>24 your problem with the definition appears to be the word</p> <p>25 "perfect," which doesn't actually appear in the</p>
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<p>1 A. Yes.</p> <p>2 Q. You'd agree with me that they are a</p> <p>3 reliable source --</p> <p>4 A. So this is from 1977?</p> <p>5 Q. Yes. You'd agree with me that the Bureau</p> <p>6 of Mines is a reliable source of information for</p> <p>7 geological term -- geological --</p> <p>8 A. I am somewhat hesitant's to make a</p> <p>9 generalization of any organization being extremely</p> <p>10 reliable or not. It depends on the individual. But,</p> <p>11 generally, many things that have been produced are</p> <p>12 reliable. This document is from 1977, which is sort of</p> <p>13 the end of the heyday of asbestos production. So right</p> <p>14 around this time, essentially, it was coming to light</p> <p>15 that asbestos really did have a lot of hazards</p> <p>16 associated with it.</p> <p>17 Q. Can you please turn to page 30 of this</p> <p>18 report? Specifically, there's a the paragraph, it's</p> <p>19 called "Cleavage Fragment." Do you see where I'm</p> <p>20 talking about?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. If you go down to the second -- I</p> <p>23 can read the first few on, but -- I'll read all of it</p> <p>24 for clarity. "Cleavage fragment: A fragment produced</p> <p>25 by the breaking of crystals in" direct -- in "directions</p>	<p>1 definition. But you generally agree that a cleavage</p> <p>2 fragment is a cleave along a generally parallel plane of</p> <p>3 a crystalline structure, right?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. If you continue along, it says,</p> <p>6 "Minerals" --</p> <p>7 A. It says "with perfect cleavage."</p> <p>8 Q. That's in the next, you know, paragraph.</p> <p>9 A. I'm sorry. I got confused.</p> <p>10 Q. So it talks a little bit, you know, about</p> <p>11 it. It talks about amphiboles, et cetera. What I'm</p> <p>12 concerned is the next paragraph down. It starts,</p> <p>13 "However, because they did not grow as fibers, they</p> <p>14 cannot have characteristics of fibers. Consequently,</p> <p>15 cleavage fragments cannot be called fibers."</p> <p>16 Do you see where the Bureau of Mines has</p> <p>17 said that?</p> <p>18 MS. SCOTT: Object to form.</p> <p>19 A. So it's my professional opinion that</p> <p>20 that's inaccurate. I mean, the crystallographic -- you</p> <p>21 know, from the materials aspect of things, whether</p> <p>22 something has grown or not, you know, doesn't -- it</p> <p>23 really doesn't matter too much as far as what it is. So</p> <p>24 and -- and so, "However, because they did not grow as</p> <p>25 fibers, they cannot have characteristics of fibers."</p>

23 (Pages 86 to 89)

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<p>1 Well, you know, if you can cleave or process something, 2 roll it such that, you know, you get particle size 3 reduction, and that particle size is then, matches, 4 although perhaps there is disagreement on what 5 asbestiform is, but it matches what a fiber is, then 6 that's -- 7 BY MR. FROST: 8 Q. But, again, you can't point me to a 9 single study or peer-reviewed piece of literature that 10 supports your opinion, correct? 11 MS. SCOTT: Objection. 12 A. I think it's -- I think it's a very much 13 a reasonable interpretation. It's almost too basic, in 14 a way. I mean, if we know -- we're taught, actually, at 15 the introductory level, that minerals cleavage is the 16 first things we teach, and essentially cleavage is an 17 interval property of a given mineral, and then you can 18 reduce it, and that's why minerals, when you crush a 19 mineral, you actually, you have sort of the same general 20 kind of particle shape. So you take mica, for example, 21 and you crush it and you get a particle size reduction, 22 and a lot of that is happening along the cleavage 23 planes. So I think -- 24 BY MR. FROST: 25 Q. So that's what I established. So you</p>	<p>1 A. Yes, I believe this is what's cited in 2 the report. This is the 2010 IARC. 3 Q. Can you please turn to page 277? If you 4 look at the bottom paragraph, it says, "Asbestos is a 5 commercial term that describes six minerals that occur 6 in the asbestiform habit: Actinolite, anthophyllite, 7 chrysotile, grunerite, riebeckite and tremolite (IARC, 8 1977). Similarly to talc, these six minerals occur more 9 commonly in a non-asbestiform habit and may also be 10 elongated without being asbestiform." And then if you 11 follow down, it says, "when asbestiform, they constitute 12 asbestos and, when not asbestiform, they are referred to 13 as mineral fragments or cleavage fragments." 14 So, again, here, IARC is talking about 15 how the crystal forms or how it grows to distinguish 16 asbestiform versus cleavage fragment, correct? 17 MS. SCOTT: Objection. 18 A. So you're saying as it forms? 19 BY MR. FROST: 20 Q. Yes. 21 A. So mechanical processes can be how a 22 mineral is formed or how a texture is developed. 23 Q. So you're saying the cleave of a 24 prismatic crystal can considered the morphology of how 25 that crystal forms?</p>
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<p>1 think IRSST is wrong. You think the Bureau of Mines is 2 wrong, right? 3 MS. SCOTT: Objection. 4 BY MR. FROST: 5 Q. Why don't we look at the World Health 6 Organization? 7 MR. FROST: This is -- I'll mark this as 8 Exhibit 5. 9 MS. O'DELL: Monograph 93. 10 MR. FROST: Yes, it's Monograph 93. 11 Sorry. 12 (Exhibit 5 was marked for 13 identification.) 14 A. So this would be IARC 2010. 15 MR. FROST: Does anyone need a copy or 16 pull it up on your computer? 17 MS. SCOTT: Yeah. 18 MR. FROST: That's a better way to look 19 at it. 20 MR. FERGUSON: I'll take one, Jack, if 21 you've got an extra one. 22 MR. FROST: I do. 23 MR. FERGUSON: Lighten your load. 24 BY MR. FROST: 25 Q. Are you familiar with this publication?</p>	<p>1 A. No. You said how a mineral -- what did 2 you say? 3 Q. Yes, that's what I said is how a mineral 4 forms. This is what they're saying: A mineral can 5 form -- 6 A. So -- 7 Q. -- an asbestiform habit or not. 8 A. -- form is not growth. Form is not 9 growth. 10 Q. Okay. Fine. It's saying here that how a 11 crystal grows or develops determines whether or not it's 12 is a mineral fragment or asbestiform, correct? 13 MS. SCOTT: Objection. 14 MS. O'DELL: Object to the form. 15 A. "When asbestiform, they constitute 16 asbestos, and when not asbestiform, they are referred to 17 as mineral fragments or cleavage fragments." That's how 18 they are referred to. But I don't see anything in here 19 about growth. There's nothing about precipitating out 20 of a solution. There's nothing precipitating out of a 21 melt. There's nothing precipitating from some 22 mineralogical transformation. So -- and, again, you 23 know -- 24 BY MR. FROST: 25 Q. But, again, I just want to go back.</p>

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<p style="text-align: right;">Page 94</p> <p>1 A. -- cleavage --</p> <p>2 MR. LAPINSKI: Let him finish his answer.</p> <p>3 MR. FROST: Sure.</p> <p>4 A. Whether something is a cleavage or</p> <p>5 fragment or not, it can be -- it can match the</p> <p>6 dimensions of something that is defined by NIOSH or</p> <p>7 other things. It can be 1 micron by 3 microns or it can</p> <p>8 be 1 micron by 5 microns. So I don't -- the -- you</p> <p>9 know. But this, this doesn't seem to -- you keep</p> <p>10 implying that there has to be growth for the mineral to</p> <p>11 occur, but it's not -- apparently, in here, it doesn't,</p> <p>12 it doesn't make that stipulation.</p> <p>13 Grinding, grinding can be one method, and</p> <p>14 then deformation. We have other examples where,</p> <p>15 essentially, textures are developed from deformation,</p> <p>16 meteorite impacts. We have metamorphic rocks. We can</p> <p>17 have, essentially, high temperature or high pressure</p> <p>18 metamorphic rocks that have one form of quartz in them.</p> <p>19 Then when they get exhumed, essentially, they shatter</p> <p>20 the granite around them and create a different texture.</p> <p>21 So I don't, I don't think that growth is</p> <p>22 necessarily related to -- I think, in my professional</p> <p>23 opinion, it's not related to the generation of cleavage</p> <p>24 fragments, and it's my professional opinion that</p> <p>25 cleavage fragments can have asbestiform materials.</p>	<p style="text-align: right;">Page 96</p> <p>1 question.</p> <p>2 A. -- activity --</p> <p>3 Q. Let me ask you a question. Let me ask</p> <p>4 you the question without reading from the thing, because</p> <p>5 you're reading the phonetics, which aren't actually the</p> <p>6 question I'm asking.</p> <p>7 A. Okay. I'm sorry.</p> <p>8 Q. What properties, other than size, will</p> <p>9 tell you whether or not a particle is a cleavage</p> <p>10 fragment versus an asbestiform fiber?</p> <p>11 A. What properties other than size?</p> <p>12 Q. I guess size truly -- is that what</p> <p>13 determines whether or not a particle is asbestiform</p> <p>14 versus a cleavage fragment, in your opinion?</p> <p>15 MS. SCOTT: Objection.</p> <p>16 A. It's a major, a major factor in it. But,</p> <p>17 you know, you can have things that are large that are</p> <p>18 asbestiform as well. So hand samples, images in --</p> <p>19 Q. Okay. Can you answer my question? Is it</p> <p>20 a major component or is that the difference? And if</p> <p>21 there's more than just size, what are the other things</p> <p>22 you look at to determine whether or not a particle is a</p> <p>23 cleavage fragment versus an asbestiform fiber?</p> <p>24 MS. SCOTT: Objection. He is answering</p> <p>25 your question. Go ahead, Doctor.</p>
<p style="text-align: right;">Page 95</p> <p>1 The other thing that confuses things is</p> <p>2 you can have a cleavage fragment that's a meter, right?</p> <p>3 You can -- you can have large crystals. You can go out</p> <p>4 to the South Dakota mines and pick up a spodumene, hit</p> <p>5 it with a hammer. That's a cleavage fragment. Because</p> <p>6 we have these same atomic laws, essentially, you get the</p> <p>7 same type of effects into the small particle ranges.</p> <p>8 Q. So now I'll go back to the same question</p> <p>9 I asked before you couldn't answer, and that was, other</p> <p>10 than size, other than this whole idea of aspect ratio,</p> <p>11 what other differences can you tell me there is between</p> <p>12 an asbestiform fiber and a cleavage fragment? Is it</p> <p>13 truly just size, in your opinion, that makes something</p> <p>14 asbestiform?</p> <p>15 MS. SCOTT: Object to the form of the</p> <p>16 question. You can answer.</p> <p>17 BY MR. FROST:</p> <p>18 Q. It's an easy enough question. I'll ask</p> <p>19 it a different way if you want.</p> <p>20 A. I'm a slow reader. Sorry. What</p> <p>21 differences can you tell me there is between asbestiform</p> <p>22 fiber around achieve advantage fragment -- a cleavage</p> <p>23 fragment. So if you're talking about just differences</p> <p>24 in general --</p> <p>25 Q. Well, no. That's why. Let me ask you a</p>	<p style="text-align: right;">Page 97</p> <p>1 BY MR. FROST:</p> <p>2 Q. I don't understand how telling me the</p> <p>3 size of giant pattern, giant rocks that are grabbed from</p> <p>4 somewhere else. What I want to know are what properties</p> <p>5 do you look at when you're trying to determine if it's</p> <p>6 an asbestiform fiber versus a cleavage fragment? Is it</p> <p>7 just the size of the mineral with -- you know, the</p> <p>8 aspect ratio of the mineral? Is that purely what</p> <p>9 determines, in your opinion, whether a particle is</p> <p>10 asbestiform versus cleavage?</p> <p>11 A. That and the texture.</p> <p>12 Q. What do you mean by "texture"? What</p> <p>13 properties are you looking at in the texture?</p> <p>14 A. The texture is how -- is the size, shape</p> <p>15 and distribution of materials.</p> <p>16 Q. So, again, we're talking about size,</p> <p>17 shape and distribution. These are the only -- these are</p> <p>18 the aspects --</p> <p>19 A. I get that from -- I'm sorry.</p> <p>20 Q. I was going to say, size, shape and</p> <p>21 distribution are the attributes you look at to determine</p> <p>22 whether or not a particle is asbestiform versus</p> <p>23 cleavage?</p> <p>24 A. A spatial distribution is not necessarily</p> <p>25 size and shape.</p>

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<p style="text-align: right;">Page 98</p> <p>1 Q. What do you mean by "spatial 2 distribution," then? 3 A. The occurrence of it in a sample or 4 substrate. 5 Q. What do you mean by "occurrence of it in 6 a sample or substrate"? 7 A. The placement of it. So, essentially, we 8 can have a lithology onto which, relative to that, an 9 asbestiform material occurs. 10 Q. What do you mean by lithology upon which 11 an asbestiform material occurs? 12 A. Lithology is a general term for a type of 13 rock. It's a very general term for a type of rock. 14 Q. Okay. So, effectively, you're saying the 15 type of rock it is and the size and shape of the 16 particle determine whether or not it's asbestiform? 17 Those are the three considerations you look at? 18 A. Well, so, not necessarily, but, you know, 19 I'm talking about hand sample size. 20 Q. Okay. And this is -- and what about -- 21 and what about micron size, when you're looking at a 22 particle that's micron size? 23 A. Aspect ratio is important. I think that 24 and -- so to identify a fiber or a cleavage fragment, to 25 thoroughly identify things, one should generally do,</p>	<p style="text-align: right;">Page 100</p> <p>1 between a cleavage fragment and an asbestiform fiber? 2 Q. Yes. 3 A. A cleavage fragment can be a subset of 4 asbestiform fibers. 5 Q. So you're telling me there's no 6 difference between a cleavage fragment and asbestiform 7 fiber if it's -- 8 A. No. 9 Q. -- if they're the same size? 10 A. If it's -- 11 MS. SCOTT: Let him finish. 12 BY MR. FROST: 13 Q. If they meet whatever aspect ratio 14 definition you want to put on it, as far as you're 15 concerned, any cleavage fragment that meets that 16 definition is an asbestiform fiber? 17 MS. SCOTT: Objection. 18 A. Speculative in that I don't -- you know, 19 I don't -- 20 BY MR. FROST: 21 Q. It's not speculative. I'm asking for 22 your definition. 23 A. I'm sorry. I have an incomplete thought. 24 A cleavage fragment can be a subset of -- it can be a 25 subset of an asbestiform fiber.</p>
<p style="text-align: right;">Page 99</p> <p>1 should do TEM work. And in order for that data to be 2 interpreted, to identify the aspect ratio and also what 3 the material is, you need to do imaging electron 4 diffraction and electron microscopy. 5 Q. Okay. I fear you're not understanding my 6 question. I'm not -- I want to know what the difference 7 is between an asbestiform particle and a cleavage 8 fragment. Is it purely the aspect ratio and the type of 9 rock it's generated from, in your opinion? 10 MS. SCOTT: Objection. 11 A. I'm sorry. I'm having difficulty 12 describing it. I thought I described it. I thought I 13 answered. 14 BY MR. FROST: 15 Q. What you keep saying is you keep telling 16 me is that aspect ratio is a major component. Is it the 17 only component? Are there others? We've heard the type 18 of rock. Are there any other things you would look at 19 to tell me these are the properties of an asbestiform 20 fiber versus these are the properties of a cleavage 21 fragment? I'm just asking for simple mineralogic 22 definition here of what's the difference between a 23 cleavage fragment and an asbestiform fiber. If it's 24 rock type and aspect ratio, that's fine. 25 A. So, okay. So what's the difference</p>	<p style="text-align: right;">Page 101</p> <p>1 Q. How? Like how do you -- so what -- okay. 2 A. Based on the size and the dimensions that 3 are provided in the paragraph in page 4. 4 Q. Okay. So it's purely size and dimension 5 is what determines whether or not a cleavage fragment is 6 a subset of asbestiform? 7 A. Correct. 8 Q. That's your opinion? 9 MS. SCOTT: Objection. 10 A. With respect to only my -- so I think 11 some of our confusion is I'm talking about minerals 12 in general, so things, you know, you would see in a 13 museum. And then there's, essentially, the microscopic 14 scale. 15 BY MR. FROST: 16 Q. Okay. So there's a -- how you define 17 asbestiform is different depending on whether or not 18 it's a hand sample versus something you look at in a 19 microscope? 20 A. Potentially, and things can, you know, 21 appear to be asbestiform, but they are pseudomorphs. 22 Q. Okay. So other than size, which we've 23 now determined is aspect ratio, you can't tell me any 24 other properties that you would look at to determine 25 whether or not a particle, an elongated mineral</p>

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<p style="text-align: right;">Page 102</p> <p>1 particle, is a cleavage fragment versus an asbestiform 2 fragment. Is that -- is that a fair summary of your 3 opinion? 4 A. I'm unsure. I'm sorry. I'm tired. 5 The -- if it -- so the -- so in your question, mineral 6 type doesn't matter, correct? 7 Q. I don't know. I'm asking you how you 8 define. Does mineral type matter for asbestiform versus 9 non-asbestiform? 10 A. Well, there are minerals that tend to be 11 asbestiform or can be asbestiform and not. So, but 12 that's not necessarily related to the -- asbestiform is 13 a descriptor of the minerals, not necessarily -- so I 14 would use what, what I have in the report, basically. I 15 would say that a cleavage fragment can be an asbestiform 16 particle and size. The aspect ratio is a major 17 contributor. 18 Also, the -- you know, if it is a -- so, 19 for example, if the chemistry and the electron 20 diffraction data and the images also indicate that it is 21 a mineral that is known to be asbestos, I think that 22 that would be -- that would support that. 23 I think that, you know, if you had -- 24 it's like kyanite, for example, might -- kyanite might 25 have -- meet those dimension, fiber-dimension</p>	<p style="text-align: right;">Page 104</p> <p>1 first, it has to be of a rock that could be asbestiform, 2 and then the major component is the size, meaning aspect 3 ratio. Is that a fair summary of the definition you're 4 giving me? 5 A. I'm not sure. I'm sorry. I'm spacing 6 out a little bit. A cleavage fragment can be 7 asbestiform. 8 Q. Okay. But what I keep asking you is -- 9 A. The criteria? 10 Q. The criteria you're using to define 11 something as asbestiform, is it purely rock type, that 12 is, a type of rock that can be asbestiform? 13 A. I -- 14 Q. Hold on. That's one. 15 A. Okay. 16 Q. And then the other, which is the major 17 component, is the size, meaning the aspect ratio of the 18 particle. Are those the two things you look at when 19 you're determining whether or not a particle is an 20 asbestiform fiber? 21 A. I would sort of correct myself in saying 22 the particle size and the mineralogy. 23 Q. Okay. Particle size and mineralogy. And 24 mineralogy, meaning the type of mineral it is, correct? 25 A. Yes.</p>
<p style="text-align: right;">Page 103</p> <p>1 requirements, but because it is kyanite, it wouldn't 2 necessarily be described as asbestiform, but it would be 3 a fiber. So there's complexities. 4 Q. Okay. So I think we have -- I'll change 5 my summary of your opinion. So in determining whether 6 or not an elongated mineral particle, and we can agree 7 an elongated mineral particle is a particle that, you 8 know, broke off of something that's long, right? Can we 9 agree on that? 10 A. Yes. 11 Q. Okay. So in order to determine if an 12 elongated mineral particle is a cleavage fragment or 13 asbestiform fiber, the two things you look at are, 14 first, whether or not it's a rock that can be 15 asbestiform, and then, second, which is the major 16 component, is its size, meaning aspect ratio. Is that a 17 fair summary of your opinion? 18 A. Well, so that's a different question. So 19 elongated mineral particle -- 20 Q. Then if elongated mineral particle's 21 confusing you, I'll take that out. 22 So if we're trying to figure out if a 23 particle -- I don't care what size, I don't care if it's 24 elongated or not. If we're trying to figure out if a 25 particle is a cleavage fragment or an asbestiform fiber,</p>	<p style="text-align: right;">Page 105</p> <p>1 Q. Okay. And, again, the basis of your 2 opinion that that's the definition of asbestiform comes 3 from your coursework and undergraduate and graduate, 4 correct? 5 A. Yes. 6 Q. And sitting here today, you can't cite me 7 a single study in the peer-reviewed literature or from 8 any government organization that supports that theory, 9 correct? 10 MS. SCOTT: Objection. 11 MS. O'DELL: Objection. Form. 12 A. So -- 13 BY MR. FROST: 14 Q. I'm just asking for citations. 15 MR. LAPINSKI: Let him finish. 16 A. I cannot -- I cannot -- let me think how 17 to phrase this. Peer review, I have had discussions, 18 actually, with my -- a former committee member, Bill 19 Mull. He was on my Ph.D. committee, and we had several 20 discussions about impurities and things like that and 21 industrial minerals. He was an industry guy. 22 And, basically, we talked about small 23 particles breaking off and how that could be of concern 24 in different ways. And then I've had discussions in 25 industry about, essentially, fine particles getting</p>

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<p>1 entrained in things with another company, one based here</p> <p>2 in Cincinnati, not basically asbestiform, not basically</p> <p>3 asbestos, but there's graphite and biotite.</p> <p>4 So no peer-review literature, but I've</p> <p>5 had discussions in a general sense, but not specific to</p> <p>6 talc, but with contaminants, small particles breaking.</p> <p>7 Q. So the basis --</p> <p>8 A. So I think companies sometimes use</p> <p>9 different -- it's actually common for companies to use</p> <p>10 different words. They have internal vocabularies, even,</p> <p>11 you know, so that might be the issue.</p> <p>12 BY MR. FROST:</p> <p>13 Q. So it's based off your coursework and</p> <p>14 discussions with industry individuals but not any</p> <p>15 peer-reviewed literature?</p> <p>16 MS. SCOTT: Objection.</p> <p>17 A. Yes. Correct.</p> <p>18 BY MR. FROST:</p> <p>19 Q. All right. We're going to move to</p> <p>20 another definition. Okay?</p> <p>21 A. Okay.</p> <p>22 Q. I note in your report -- let me find</p> <p>23 where it is. At the top, under the section that says</p> <p>24 "Asbestos" on page 4. Second sentence, you say,</p> <p>25 "Asbestos is a naturally occurring mineral that can be</p>	<p>1 definition, according to the paragraph?</p> <p>2 A. I'm just saying that's what they define</p> <p>3 those as.</p> <p>4 Q. Do you believe you've included the whole</p> <p>5 definition that ATSDR has of asbestos in your paper?</p> <p>6 MS. SCOTT: Objection.</p> <p>7 A. I believe it's consistent with a document</p> <p>8 I've done. I was gonna say, there are other academic</p> <p>9 classifications. Sometimes I know, in my classwork, it</p> <p>10 was discussed like antigorite sometimes comes up.</p> <p>11 Antigorite is actually something that's detected in some</p> <p>12 of the documents as well. So antigorite can be, look</p> <p>13 like it's asbestos, but it's not officially classified.</p> <p>14 So there's some con -- if you look in the</p> <p>15 older literature, there's some confusion. People will</p> <p>16 also refer to other minerals, perhaps incorrectly, as</p> <p>17 being asbestos. So it's -- historically, I think it can</p> <p>18 be a term that is applied either too loosely or things</p> <p>19 just haven't worked out, so...</p> <p>20 BY MR. FROST:</p> <p>21 Q. And the definition of asbestos in the</p> <p>22 ATSDR, is that something you found yourself or was that</p> <p>23 given to you by plaintiffs' counsel?</p> <p>24 MS. SCOTT: Objection.</p> <p>25 A. I looked at -- ATSDR is something that</p>
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<p>1 in close proximity to talc in mines around the world."</p> <p>2 Is asbestos a mineral?</p> <p>3 A. I'm sorry. It should be mineral group.</p> <p>4 Q. Okay. That was going to be my next</p> <p>5 question. Asbestos is a defined group of minerals,</p> <p>6 correct?</p> <p>7 A. Yeah. It can be referred to that.</p> <p>8 Q. Okay. Without looking at your report,</p> <p>9 can you tell me what minerals fit the definition of</p> <p>10 asbestos?</p> <p>11 MS. SCOTT: Objection.</p> <p>12 A. Tremolite, crocidolite, anthophyllite,</p> <p>13 chrysotile, amosite.</p> <p>14 BY MR. FROST:</p> <p>15 Q. And in your report, you know, you list</p> <p>16 them. I believe it's here on page 4. You list the</p> <p>17 amphibole class includes, you know, amosite,</p> <p>18 crocidolite, actinolite, anthophyllite and tremolite,</p> <p>19 correct?</p> <p>20 A. I'm sorry. Where?</p> <p>21 MS. SCOTT: Here.</p> <p>22 BY MR. FROST:</p> <p>23 Q. Page 4.</p> <p>24 A. Yeah. So, yeah, end of the second line.</p> <p>25 Q. And you're relying on the ATSDR for this</p>	<p>1 I've used in the past for my publications in general, so</p> <p>2 I'm familiar with them. So we use that in a variety of</p> <p>3 ways to help frame our discussions in peer-review</p> <p>4 articles and things like that.</p> <p>5 BY MR. FROST:</p> <p>6 Q. All right. I'm going to mark this next</p> <p>7 exhibit. I think we're on six.</p> <p>8 MS. SCOTT: Yes.</p> <p>9 MR. FROST: Yep.</p> <p>10 (Exhibit 6 was marked for</p> <p>11 identification.)</p> <p>12 MR. FROST: Do you need a copy?</p> <p>13 MR. FERGUSON: I'll take it unless</p> <p>14 anybody else wants one.</p> <p>15 MS. O'DELL: Have you directed us to a</p> <p>16 page?</p> <p>17 MR. FROST: He was looking at his</p> <p>18 references to make sure. I think he's</p> <p>19 identifying that it's the same article.</p> <p>20 A. I'm not -- I'm not sure if this is Item</p> <p>21 Number 6.</p> <p>22 BY MR. FROST:</p> <p>23 Q. Well, here. I can speed this up. You</p> <p>24 agree with me that this is an ATSD article, correct?</p> <p>25 A. Yes.</p>

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<p>1 Q. Okay. Turn to -- actually, it's page 1. 2 It's a misnomer. It's decently into it, probably about 3 10 or 15 pages into it. As I said, the one is a 4 misnomer. Okay. 5 MS. SCOTT: I have a -- 6 MR. FROST: Yeah. I was going to say, I 7 apologize for it being highlighted, but I'm 8 going to read the highlighted parts anyway, so 9 it will help guide us there. That was a 10 printing issue. 11 BY MR. FROST: 12 Q. Do you see where it defines, under 13 Section 1.1, "What is Asbestos"? 14 A. Yes, I do. 15 Q. Do you notice that its definition of 16 asbestos are "the fibrous varieties of tremolite, 17 actinolite and anthophyllite that occur naturally in the 18 environment"? 19 MS. SCOTT: Objection. 20 A. I see that, yeah. 21 BY MR. FROST: 22 Q. That's slightly different than what you 23 attribute the definition of asbestos from the ATSDR in 24 your report, right? You don't note that it's the 25 fibrous varieties of the amosite, crocidolite,</p>	<p>1 statement. 2 MR. FROST: Sure. 3 MS. SCOTT: Go ahead. 4 BY MR. FROST: 5 Q. Do you see the second highlighted portion 6 on that page? It starts at the bottom. "Asbestos 7 minerals consist of thin, separable fibers that have a 8 parallel arrangement. Nonfibrous forms of tremolite, 9 actinolite and anthophyllite are found naturally. 10 However, because they are not fibrous, they are not 11 classified as an asbestos mineral." That's different 12 than what you're telling us here, correct? 13 A. Let me compare. 14 Q. Well, that's what you just told us, that 15 you could have nonfibrous tremolite and it would still 16 be asbestos. 17 A. I'm sorry. What was the question again? 18 This is not consistent with what I have written? 19 Q. I'm saying it's not consistent with what 20 you just told me. You just told me the fibers doesn't 21 really matter because you can have -- 22 A. Fibers -- 23 Q. So my question is: You're relying on -- 24 say you rely on the ATSDR as the definition for 25 asbestos, but your definition of asbestos, sitting here</p>
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<p>1 actinolite, anthophyllite and tremolite, correct? 2 A. Let me just double-check. 3 Q. It's page 4. 4 A. In two general classes. I omitted the 5 word "fibrous," but it seems that the minerals are 6 consistent. 7 Q. Yeah, the minerals are consistent, but 8 isn't the omission of "fibrous" an important distinction 9 in the definition of what's asbestos and what isn't? 10 MS. SCOTT: Objection. 11 A. In the context of this situation, I 12 don't -- I don't think it exclusively applies because 13 you can mechanically produce particles that are -- meet 14 the criteria on the bottom of the last paragraph on page 15 4. So tremolite -- and actually, you know, on one hand, 16 IARC 2012 lists tremolite as a carcinogen in general. 17 So IARC is not -- I was consistent, but you're correct. 18 I did not use the word "fibrous." 19 BY MR. FROST: 20 Q. So you're not consistent, because you're 21 saying ATSDR defines asbestos, and then you need to put 22 them out. But you fail to leave out that these are 23 fibrous. I'll tell you why it's important. Do you see 24 the second highlighted portion? 25 MS. SCOTT: Let me just object to the</p>	<p>1 today, is actually different than that of the ATSDR. So 2 it doesn't really support what you're saying today, 3 correct? 4 MS. SCOTT: Objection. Misrepresents. 5 A. No. I think that is a misrepresentation. 6 So I cited this, and the minerals are listed here are 7 the same minerals there. 8 BY MR. FROST: 9 Q. Okay. 10 A. And then, based on my academic 11 experience, knowledge, these minerals are also, you 12 know, what I would list as well. 13 Q. But that's not -- you didn't say they say 14 that certain types of these minerals can be asbestos. 15 The definition that you attribute, and you're talking 16 today about asbestos, is different than the -- you say 17 the ATSDR supports your definition of asbestos, but 18 yours is actually slightly different than theirs, right? 19 MS. SCOTT: Objection. Misrepresents. 20 A. I left out a word. 21 BY MR. FROST: 22 Q. And according to them, it's an important 23 word, because as the ATSDR says, "Because they are not 24 fibrous, they are not classified as asbestos minerals." 25 Do you agree?</p>

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<p>1 MS. SCOTT: Objection.</p> <p>2 A. That's what's stated in the document.</p> <p>3 BY MR. FROST:</p> <p>4 Q. Okay. Let's move down to the third</p> <p>5 paragraph under "Asbestos" in your report. Do you see</p> <p>6 the -- I don't know. What sentence is it? Third</p> <p>7 sentence starts, "However, non-asbestiform cleavage</p> <p>8 particles can correspond to the definition of respirable</p> <p>9 fiber as defined by WHO and, due to its morphology, can</p> <p>10 have potentially dangerous health effects." Do you see</p> <p>11 that?</p> <p>12 A. Yes.</p> <p>13 Q. Now, you don't have an opinion yourself</p> <p>14 as to whether or not asbestiform can cause any disease.</p> <p>15 You're not a doctor, right?</p> <p>16 A. Correct.</p> <p>17 Q. And you're relying on, you know, other</p> <p>18 documents and things you've read for that statement?</p> <p>19 That's correct?</p> <p>20 A. Correct.</p> <p>21 Q. Do you have any opinion on whether or not</p> <p>22 the surface chemistries of cleavage fragments versus</p> <p>23 asbestiform fibers are the same?</p> <p>24 A. I'm not a surface geochemist.</p> <p>25 Q. Okay. Do you agree with me that IARC has</p>	<p>1 morphology can have potentially dangerous health</p> <p>2 effects?</p> <p>3 A. Yes, I say those documents.</p> <p>4 Q. Okay. Let's look at the NIOSH road map.</p> <p>5 MR. FROST: Did you mark that yet?</p> <p>6 (Exhibit 7 was marked for</p> <p>7 identification.)</p> <p>8 BY MR. FROST:</p> <p>9 Q. Do you recognize this as the NIOSH</p> <p>10 document that you were relying on for your statement?</p> <p>11 MS. SCOTT: Jack, can you, just for my</p> <p>12 ease, can you direct me to the citation within</p> <p>13 the report?</p> <p>14 MR. FROST: That I'm going to go to?</p> <p>15 MS. SCOTT: Yeah.</p> <p>16 MR. FROST: I'm going to page 5, or V,</p> <p>17 which is the Executive Summary.</p> <p>18 MS. O'DELL: Thank you. You're talking</p> <p>19 about in the NIOSH document?</p> <p>20 MR. FROST: Oh, in his?</p> <p>21 MS. O'DELL: Yes.</p> <p>22 MR. FROST: It's on page 4, third</p> <p>23 paragraph down from Asbestos. It's NIOSH 2010,</p> <p>24 IRSST 2012.</p> <p>25 MS. SCOTT: Thank you.</p>
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<p>1 ultimately determined that non-asbestiform cleavage</p> <p>2 fragments actually are not or do not -- sorry. Let me</p> <p>3 reform that.</p> <p>4 Could we also agree that IARC has</p> <p>5 determined that non-asbestiform minerals are not</p> <p>6 carcinogenic?</p> <p>7 MS. SCOTT: Objection.</p> <p>8 A. I believe IARC 2012 lists tremolite as a</p> <p>9 carcinogen.</p> <p>10 BY MR. FROST:</p> <p>11 Q. And do you know what level of carcinogen?</p> <p>12 Do you know what category?</p> <p>13 MS. O'DELL: Objection to form.</p> <p>14 A. I don't specifically remember. I know</p> <p>15 there are three categories that are relevant. There's</p> <p>16 Group 1, and then Group 2-A and 2-B. Group 1 are known</p> <p>17 carcinogens. 2-A is probable, and I think 2-B is</p> <p>18 possible. But, again, I'm kind of --</p> <p>19 BY MR. FROST:</p> <p>20 Q. That's not your -- that's not your field</p> <p>21 of expertise?</p> <p>22 A. That's not my area.</p> <p>23 Q. And you also -- so you cite the NIOSH</p> <p>24 2010. You also cite the IRSST 2012, correct, for your</p> <p>25 proposition that these, the fragments of the same</p>	<p>1 A. I'm not seeing it in my list.</p> <p>2 BY MR. FROST:</p> <p>3 Q. Well, yeah. But if you look at page 4 of</p> <p>4 your report, you cite to NIOSH 2012 for the proposition</p> <p>5 that --</p> <p>6 A. Wait. Okay.</p> <p>7 Q. -- non-asbestiform cleavage fragments can</p> <p>8 have the same potentially dangerous health effects. If</p> <p>9 you turn to page V, "Executive Summary."</p> <p>10 A. Page V. Okay. "Executive Summary."</p> <p>11 Q. The second paragraph, about halfway down,</p> <p>12 there's a sentence that starts, "Asbestos fibers are</p> <p>13 clearly a substantial health concern."</p> <p>14 A. Let me find it. Okay. I found it.</p> <p>15 Q. After that, it reads, "Further research</p> <p>16 is needed to better understand health risks associated</p> <p>17 with exposure to other thoracic-size EMPs, including</p> <p>18 those with mineralogical compositions identical or</p> <p>19 similar to the asbestos minerals in those that have</p> <p>20 already been documented to cause asbestos-like disease</p> <p>21 as well as the physiochemical characteristics that</p> <p>22 determine their toxicity." Did I read that correctly or</p> <p>23 close enough, anyway, I'm sure?</p> <p>24 A. Yes, yes. Yep.</p> <p>25 Q. Okay. So, again, NIOSH here isn't saying</p>

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<p>1 that -- NIOSH is not supporting the position you have in 2 your paper here, correct? NIOSH's determination is that 3 they can't make one. More research is necessary, right? 4 MS. SCOTT: Objection. 5 A. That is what's stated here. 6 BY MR. FROST: 7 Q. Let's turn back to the IRSST document. I 8 forget what we marked that as. I think it's 4. There 9 it is. If you can turn to page 37. 10 A. Okay. 11 Q. And, again, at the top nine 12 recommendations, it states, Since a conclusion cannot be 13 reached about the biological effects from the 14 distinction between a cleavage fragment and asbestos 15 fibers -- actually, I did not read that correctly. Let 16 me try again. 17 "Since a conclusion cannot be reached 18 about the biological effects from the distinction 19 between cleavage fragments and asbestos fibers," and 20 then it continues to say precautionary things. So, 21 again, they also haven't determined, as you state in 22 your report, that it has the same dangerous health 23 effects, correct? 24 MS. SCOTT: Objection. Scope. 25 A. It says what it says.</p>	<p>1 indicated, I thought there might be typos in the report. 2 Q. Okay. What's the typo? 3 A. So, essentially, the difference should be 4 diversity. Talc forms in the earth in metamorphic 5 terranes, and the diversity is metamorphosed mafic and 6 ultramafic rock deposits show the complexity of talc 7 ores at different levels. 8 Q. Okay. And -- 9 A. Sorry about that. 10 Q. That's okay. Typos happens. 11 Your support for that is Berg 1977? 12 A. Yes. 13 Q. I'll mark Berg. 14 A. It's e.g., Berg, so that's an example. 15 Q. Yes. Well, look at the one example you 16 pointed to. 17 MR. FROST: Let me see if I can find a 18 copy. Let me see if I can find a copy where the 19 staple hasn't come out. We'll mark that one. 20 Do you all need one? 21 MS. SCOTT: Sure. 22 MR. FROST: Be careful of the staple. 23 It's pokey. 24 MS. SCOTT: I appreciate that. 25 (Exhibit 8 was marked for</p>
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<p>1 BY MR. FROST: 2 Q. Yes. They come to the same conclusion as 3 NIOSH, and that's, we don't know one way or the other. 4 More research needs to be done, right? 5 A. Correct. 6 Q. Other than these two, can you point me 7 right now to any other studies that actually support the 8 sentence you have here in your report that cleavage 9 fragments are the same, have the same dangerous health 10 effects as asbestiform fibers? 11 A. No. 12 Q. All right. If we move down, further down 13 to page 4 of your report, the section called "Formation 14 of Talc deposits and inherent asbestos impurities." 15 A. Okay. 16 Q. The first sentence, "Talc forms in the 17 earth in metamorphic terranes, and the difference is 18 metamorphosed" -- I apologize. Can tell me how to 19 pronounce that word? 20 A. Metamorphosed. 21 Q. Metamorphosed. Okay. "And the 22 difference in metamorphosed mafic and ultramafic rock 23 deposits show the complexity of talc ores at different 24 levels." 25 A. I'm sorry. That's a typo. As I</p>	<p>1 identification.) 2 BY MR. FROST: 3 Q. Do we agree this is the Berg '77 you 4 reference in your report? 5 A. I'm not a hundred percent sure. 6 Q. It also appears, if you look at 18 -- 7 MS. O'DELL: Excuse me, Doctor. Are you 8 finished? Did you finish with your answer? 9 A. I'm not sure. So either I might have 10 misquoted something. Let's see. I don't think I -- I 11 don't think I have it. Let me -- 12 BY MR. FROST: 13 Q. We can look at it during a break. We can 14 come back. 15 A. I'll check. Berg had several. 16 Q. I believe it's number 18. 17 A. So I am not a hundred percent sure. I 18 might have misquoted -- 19 Q. Okay. 20 A. -- this. Because, as I remember the 21 book, it was -- I honestly don't think I -- 22 Q. Looked different? 23 A. Yeah. It was -- yeah. I think I've 24 looked at some of this before. It looks familiar, but 25 the thing that I'm thinking, I think I misquoted. I'm</p>

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<p style="text-align: right;">Page 122</p> <p>1 sorry.</p> <p>2 Q. If I were to tell you that talc isn't</p> <p>3 even mentioned in this paper --</p> <p>4 A. Yeah. I mean, there's like -- the book I</p> <p>5 had, there's images of mines that talks about, I think,</p> <p>6 the Yellowstone mines, specifically. So I'm sorry about</p> <p>7 that. I totally, totally missed that.</p> <p>8 Q. Okay. If we move down to the next</p> <p>9 sentence, you state that "Italian mines, which Johnson &</p> <p>10 Johnson and Imerys obtained talc for cosmetic</p> <p>11 production, were ultramafic origin."</p> <p>12 A. Okay.</p> <p>13 Q. Is that true?</p> <p>14 A. I believe so.</p> <p>15 Q. Can we turn back to the IARC 2010? It's</p> <p>16 the one with the orange cover. Go to page 283 to 84.</p> <p>17 A. Okay.</p> <p>18 Q. If you look at B, towards the bottom, it</p> <p>19 says, "Talc derived from magnesium carbonites."</p> <p>20 A. Okay.</p> <p>21 Q. "Talc deposits formed from the alteration</p> <p>22 of carbonite and sandy carbonite, such as dolomite and</p> <p>23 limestone, are the most important in terms of world</p> <p>24 production. Two types are recognized." And if you skip</p> <p>25 down to two, it says, "Those derived from hydrothermal</p>	<p style="text-align: right;">Page 124</p> <p>1 think --</p> <p>2 Q. You certainly didn't include it in the</p> <p>3 report, right?</p> <p>4 MS. SCOTT: Objection.</p> <p>5 A. I don't know. I forget.</p> <p>6 THE WITNESS: Can we take a break?</p> <p>7 MR. FROST: Sure.</p> <p>8 VIDEOGRAPHER: We're now going off</p> <p>9 record. The time is 12:21.</p> <p>10 (A recess was taken from 12:21 to 1:25.)</p> <p>11 VIDEOGRAPHER: We're now back on record.</p> <p>12 The time is 1:25.</p> <p>13 BY MR. FROST:</p> <p>14 Q. All right. Welcome back from lunch. We</p> <p>15 were on page 4 of your report under "Formations of</p> <p>16 Talc." And we talked about Italy. Let's move on to</p> <p>17 Vermont. You say, "Vermont mines relevant to this</p> <p>18 litigation are mafic and ultramafic origins." What's</p> <p>19 your support for that statement?</p> <p>20 A. I'm sorry. Oh, bottom of 4?</p> <p>21 Q. Yeah, bottom of 4, moving on to 5.</p> <p>22 A. It's the geology of the area.</p> <p>23 Q. Do you believe there are mafic formations</p> <p>24 of talc relevant to the Vermont mines used by Johnson &</p> <p>25 Johnson and Imerys in this case?</p>
<p style="text-align: right;">Page 123</p> <p>1 alteration (including retrograde metamorphism) of</p> <p>2 regionally *metamorphosed siliceous dolomites and other</p> <p>3 magnesium-rich rocks." And then if you turn the page</p> <p>4 over one, two, three, it says "Italy vouches own after</p> <p>5 that."</p> <p>6 A. So this is information produced by</p> <p>7 Luzenac?</p> <p>8 Q. Well, this is from IARC.</p> <p>9 A. It's in IARC, but they're citing Luzenac</p> <p>10 as part of this, and each -- the occurrences of each</p> <p>11 individual mine are -- location are not shown. IARC is</p> <p>12 more of a health thing. I would not necessarily expect</p> <p>13 a detailed analysis of a geology from an IARC monograph.</p> <p>14 So...</p> <p>15 Q. Can you point to me to any geological</p> <p>16 study that shows --</p> <p>17 MR. LAPINSKI: Counsel, let him finish</p> <p>18 his answer first.</p> <p>19 A. So, I don't think that -- I don't know</p> <p>20 what they are specifically relying on.</p> <p>21 BY MR. FROST:</p> <p>22 Q. Can you cite me any geological study that</p> <p>23 shows that the Italian mines of Val Chisone were of</p> <p>24 ultramafic origin?</p> <p>25 A. I forget the citations specifically. I</p>	<p style="text-align: right;">Page 125</p> <p>1 A. Yes.</p> <p>2 Q. And do you have a geological survey or</p> <p>3 something else you're relying on for that?</p> <p>4 A. There are USGS reports and things like</p> <p>5 that.</p> <p>6 Q. And they say mafic? They don't just say</p> <p>7 it's an ultramafic belt?</p> <p>8 A. I believe so.</p> <p>9 Q. On page 5, kick down to the next</p> <p>10 paragraph, the one that starts, "Asbestos minerals,</p> <p>11 including chrysotile, tremolite and actinolite" -- I'm</p> <p>12 sorry, "tremolite, actinolite and anthophyllite are</p> <p>13 common in talc ores." What's your basis for the</p> <p>14 statement, because it's uncited?</p> <p>15 A. It's common knowledge --</p> <p>16 Q. Can you point me to a --</p> <p>17 A. -- mineralogy.</p> <p>18 Q. Can you point me to a peer-reviewed</p> <p>19 source that states that?</p> <p>20 A. Let see here.</p> <p>21 MR. LAPINSKI: Jack, while he's looking,</p> <p>22 what was the statement from the report?</p> <p>23 MR. FROST: It's page 5, the first</p> <p>24 sentence of the first full paragraph. The</p> <p>25 "Asbestos minerals, including chrysotile,</p>

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<p>1 tremolite," et cetera. The first full 2 paragraph. 3 A. So reference 40, figure 3, is a 4 comparison I computed with silica activities. So, 5 essentially, it showed boundaries between talc and 6 chrysotile. And figure 2 shows temperature pressure 7 diagrams for chrysotile and talc. Figure 4 shows 8 comparison of computer phase equilibrium, experimental 9 data of Johannes, 1969. It shows chrysotile and talc 10 fields. So the significance of those fields is that 11 because of -- so those are fields where things, when, in 12 absolute equilibrium, those discrete phases are set or, 13 essentially, those are the phases that are stable. 14 The minerals are stable. But you can go 15 back, you know, because of geologic conditions are 16 variable, you can have metamorphism that heats up an 17 area or then cools down. You can then -- the geologic 18 conditions then can cross those phase boundaries, and 19 you essentially can have minerals that are stable for a 20 while and then revert. But, often, those reversions are 21 not necessarily complete. And to substantiate that -- 22 BY MR. FROST: 23 Q. Can I stop you right there? 24 A. Yes. 25 Q. Where does Chernoskey say that asbestos</p>	<p>1 something. That's not actually stated in this book, 2 correct? 3 MS. SCOTT: Object to the form. 4 A. The diagrams are -- that's how one can 5 interpret these diagrams. 6 BY MR. FROST: 7 Q. Okay. So -- 8 A. The field -- 9 Q. Does it say it's common? 10 MR. LAPINSKI: Counsel, let him finish 11 his answer, please. 12 MR. FROST: Sure. 13 A. So, you know, phase diagrams and the 14 interpretation of phase diagrams is something that 15 mineralogists and petrologists do all the time, and 16 basically, we often will refer to a given phase diagram. 17 People spend their entire lives perfecting phase 18 diagrams. That was typically in the '50s, '60, '70s and 19 '80s. 20 So people will actually refer to specific 21 phase diagrams by people. So one of my committee 22 members, when I was on my Ph.D., he had the best phase 23 diagram for quartz for some period of time. So we use 24 those phase diagrams. They're commonly used to 25 interpret mineral associations and assemblages.</p>
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<p>1 minerals are common in talc ores? You just told me 2 about how, chemically, things form -- 3 A. The thermodynamic diagram. I'm sorry. 4 Go ahead. 5 Q. Yes. You just told me about how 6 chemically talc forms, but where does Chernoskey talk 7 about talc ores and relate that asbestos minerals are 8 common in talc ores? 9 A. So this is a mineralogical volume, so 10 this is a review volume, and basically, talc is a 11 mineral that is in talc ores and, therefore, is 12 relevant. 13 Q. So you're telling me how talc forms, and 14 where on the pressure and temperature scale, you know, 15 it can go back and forth to, you know, tremolite. But, 16 again, does that, just because something can form in 17 nature, where does it say that asbestos minerals are 18 common in talc ores? What you're telling me -- 19 A. Well, these are -- 20 Q. -- is scientifically how talc forms. 21 A. They're commonly associated 22 thermodynamically. 23 Q. And that says that in that book? 24 A. The diagrams indicate that. 25 Q. Okay. But this is you interpreting</p>	<p>1 To further answer the question, the -- I 2 believe it's the Veblen '79. Veblen and Buseck is the 3 science paper that shows the TEM associations, you know, 4 essentially, these intergrowths of talc and chrysotile. 5 And, essentially, that literature proves the -- 6 essentially, the interpretation of the assertion I said, 7 that you go between these regions that are of one 8 condition and another. You don't necessarily get the 9 full conversion because of the kinetics. Essentially, 10 either the reaction goes too fast or things basically 11 sort of get frozen in the rock, depending upon the 12 various conditions. 13 BY MR. FROST: 14 Q. Okay. So let's be careful with the 15 language we're using here. What you're giving me is a 16 generalization about how talc, the mineral, forms, and 17 what other minerals that might be associated with that 18 formation. Is that -- is that fair? 19 A. I would be hesitant about the word 20 "generalization." I mean, these are experiments. They 21 take years. 22 Q. Okay. But -- 23 A. And the data, you know, these boundaries, 24 people in the '50s, '60s and '70s, I mean, they put a 25 great deal of effort into establishing the boundaries.</p>

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<p>1 These are relevant for understanding larger processes of</p> <p>2 metamorphism and understanding, you know, what --</p> <p>3 essentially what the history of the earth is. So the</p> <p>4 diagrams aren't generalized. They're very, very</p> <p>5 specific --</p> <p>6 Q. That's why I want you to listen very</p> <p>7 carefully to what I'm asking you. We'll really step</p> <p>8 back.</p> <p>9 All right. You agree with me, talc ore</p> <p>10 is different than talc, right? Ore means it's the</p> <p>11 deposit that is being mined, right?</p> <p>12 MS. O'DELL: Objection.</p> <p>13 A. The mineral talc is a primary --</p> <p>14 Q. But listen to the "ore."</p> <p>15 A. -- constituent --</p> <p>16 MR. LAPINSKI: Let him answer the</p> <p>17 question, Counsel.</p> <p>18 A. So the mineral talc is a primary</p> <p>19 constituent of ore, and you can't --</p> <p>20 BY MR. FROST:</p> <p>21 Q. And that's why I want you to listen to</p> <p>22 me. I'm talking about ore. Ore means it's a talc</p> <p>23 deposit that's being mined, right? You wouldn't find a</p> <p>24 piece of talc you found in somebody's backyard and call</p> <p>25 it ore, would you? Ore is a definition of a mineral</p>	<p>1 MS. SCOTT: Objection.</p> <p>2 A. You can have an ore of talc. The two are</p> <p>3 not -- so go ahead. Proceed.</p> <p>4 BY MR. FROST:</p> <p>5 Q. So where in this book is it specifically</p> <p>6 saying that talc ores, which are ores that have been,</p> <p>7 you know, talc deposits that have been determined, as</p> <p>8 you said, to be economically viable, will commonly be</p> <p>9 associated with chrysotile, tremolite, actinolite,</p> <p>10 anthophyllite?</p> <p>11 MS. SCOTT: Objection.</p> <p>12 A. The mineral constituency --</p> <p>13 BY MR. FROST:</p> <p>14 Q. So, again, you're --</p> <p>15 A. -- is -- minerals make up the talc ore.</p> <p>16 So you can't separate -- you can't separate the ore from</p> <p>17 the mineral when you're talking about how it's formed.</p> <p>18 It's integral. I mean, it's absolutely integral to the</p> <p>19 ore. You know, it would not be an ore if it didn't have</p> <p>20 talc in it, right? It wouldn't -- you have to have the</p> <p>21 required constituent in order for it to be an ore.</p> <p>22 So, therefore, you know, every</p> <p>23 petrologist in the world, every, you know, mineralogist,</p> <p>24 you know, we refer to these thermodynamic diagrams that</p> <p>25 have been worked out for, you know, now, some of them,</p>
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<p>1 that's being mined. Do you agree with me there?</p> <p>2 MS. SCOTT: Objection.</p> <p>3 A. Yeah. Ore is not necessarily a mineral.</p> <p>4 Ore can be multiple minerals.</p> <p>5 BY MR. FROST:</p> <p>6 Q. Sure. But ore is something that's being</p> <p>7 mined, right?</p> <p>8 A. Yes. It's something of economic</p> <p>9 interest --</p> <p>10 Q. Sure. So in order --</p> <p>11 A. -- as opposed to a primary material of</p> <p>12 interest.</p> <p>13 Q. Okay. So in order to be an ore, it has</p> <p>14 to be something that's being mined, right?</p> <p>15 MS. SCOTT: Objection.</p> <p>16 A. No. You can have ores that are not being</p> <p>17 mined. They're just recognized as ore deposits. I have</p> <p>18 a book of ore deposits.</p> <p>19 BY MR. FROST:</p> <p>20 Q. Okay. It's not this complicated, sir.</p> <p>21 Just listen to what I'm saying. Talc ore means</p> <p>22 something different than just a talc, you know, deposit,</p> <p>23 a talc formation somewhere. A talc ore is something</p> <p>24 that has been identified as a mineable source of talc.</p> <p>25 Are we fair on that?</p>	<p>1 you know, decades. One was '69 or whatever. So I don't</p> <p>2 think it's -- it's my professional opinion that these</p> <p>3 thermodynamic diagrams adequately relate and describe to</p> <p>4 the mineral phases that occur in talc ore.</p> <p>5 BY MR. FROST:</p> <p>6 Q. Okay. So you are making a</p> <p>7 generalization, based upon the mineral phases, that all</p> <p>8 talc ores --</p> <p>9 A. I would be hesitant to call it a</p> <p>10 generalization. I mean, it's --</p> <p>11 Q. Can I finish my question, sir?</p> <p>12 A. Yeah. I'm sorry. Sorry. Go ahead.</p> <p>13 Q. So, again, can you give me a -- can you</p> <p>14 give me a cite that shows that anthophyllite is common</p> <p>15 in every talc ore mined across the world?</p> <p>16 MS. SCOTT: Objection.</p> <p>17 A. Where does it say that in the report?</p> <p>18 Q. "Asbestos minerals, including chrysotile,</p> <p>19 tremolite and actinolite and anthophyllite are common in</p> <p>20 talc ores."</p> <p>21 A. Are common, yes. You said every talc</p> <p>22 deposit in the world.</p> <p>23 Q. Well, no. Show me where -- show me in</p> <p>24 there where it says that anthophyllite is common in</p> <p>25 every talc ore across the world.</p>

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<p>1 A. I think the interpretations of these 2 thermodynamic diagrams indicate that it's -- 3 Q. So it's purely theoretical? 4 A. No. It's experimental. 5 Q. Okay. 6 A. Is how the diagrams are designed. And 7 then, essentially, these are peer-reviewed articles that 8 are long-standing. So let me just check that to be 9 sure. Yeah, so there's, you know, these different -- so 10 Berman '88 is kind of one of these benchmark 11 thermodynamic databases, and we use these all the time 12 to understand and predict mineral stabilities and 13 understand and interpret the environments. 14 So, essentially, through the use of these 15 diagrams over time, we can interpret, you know, the 16 condition. So whether it's an ore or talc, you know, is 17 immaterial, the thermodynamics don't, don't really care. 18 Q. Well, don't you agree with me that 19 depending on the temperature, time and pressure, the 20 constituent rock of any particular deposit is going to 21 be different? I mean, that's what those phase diagrams 22 say, right? 23 MS. SCOTT: Objection. 24 A. No. The phase diagrams indicate that 25 things will be stable under different fields.</p>	<p>1 I mean, this is long recognized. 2 BY MR. FROST: 3 Q. See, that's why -- I fear you're not 4 listening to my questions. My question is: Depending 5 upon the thermodynamics that were in play in creating 6 any particular deposit, it will be different. And 7 depending on the differences, you will get different 8 mineral crystallization within the phases, correct? 9 MS. SCOTT: Object to the form. 10 A. Each situation may be slightly different. 11 But the -- to the blunt of the major phases, the 12 thermodynamics is relevant, and actually, you can 13 tweak -- you know, there's other programs that exist. 14 So, for example, on the igneous field, 15 there's a program called MELTS where you can fine tune 16 your models. And I think things were being in 17 development for these. You know, essentially, similar 18 types of things exist. There's like geochemist 19 workbench and other modeling programs that exist. 20 So, yes, you can -- things will change, 21 but these diagrams are generalizable in the sense that 22 they can be applied to multiple regions throughout 23 the -- throughout the world. 24 BY MR. FROST: 25 Q. And that's exactly what I asked you at</p>
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<p>1 BY MR. FROST: 2 Q. That's what I'm talking about. So you'll 3 have -- different minerals are stable under different 4 pressures and temperatures, right? 5 MS. SCOTT: Objection. 6 A. Not -- because of the kinetics, 7 essentially, this lag effect. You know, things are -- 8 that's not necessarily the case. So diamonds, you know, 9 the classic example that we use in courses, diamonds are 10 thermodynamically stable deep in the earth. They get 11 brought up and then they -- thermodynamically, they 12 should persist. But because of the kinetics in that 13 particular situation, the bonds of the carbon are 14 really, really strong. That diamond doesn't revert to 15 graphite. 16 So, essentially, the thermodynamics gives 17 us a guide. It is a very, very good guide. But when 18 things cross these boundaries, it takes time to 19 essentially equilibrate to the new conditions. And if 20 not enough time evolves geologically, things occur such 21 that you get these relic phases. And in the case of 22 talc ores or talc deposits or whatever you want to call 23 that, you can have essentially these relics or asbestos 24 minerals, chrysotile, for example, that co-occur. So 25 the thermodynamics basically is -- and people know that.</p>	<p>1 the very beginning is these are generalizable tables 2 that you can use to predict what's in a particular 3 deposit? 4 A. They're not tables. They're phase 5 diagrams. 6 Q. Or figures or phase diagrams. 7 A. Yeah. 8 Q. But so we're right back to where I 9 started, and that's these are generalization of how 10 phases work that you can use to predict what's in 11 something, but it's not necessarily saying there is this 12 constituent in this particular deposit, correct? 13 MS. SCOTT: Objection. 14 BY MR. FROST: 15 Q. How the phase operated will affect what's 16 in a particular deposit, right? 17 A. So it's really the combination of the 18 phase diagram. Plus, you know, I keep referring to 19 Veblen. 20 Q. Yeah. 21 A. So basically, yeah. So the phase diagram 22 is relevant when things are -- assumed to be absolutely 23 perfect when everything is in thermodynamic equilibrium. 24 Q. Yes. 25 A. And it is relevant when it's not. When</p>

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<p style="text-align: right;">Page 138</p> <p>1 things are not or when they're moving, things</p> <p>2 essentially react and progress slowly. But you can have</p> <p>3 incomplete or imperfect reactions as, you know,</p> <p>4 illustrated by the one Buseck paper, the '79 paper.</p> <p>5 Q. So if you want to predict what's in a</p> <p>6 particular deposit, you have to sort of know what the</p> <p>7 time pressure, the metamorphic history of it, when it</p> <p>8 formed, how stable it was, what it started from, what</p> <p>9 the constituent beginning minerals were, you know. Then</p> <p>10 you can apply that to a phase model?</p> <p>11 A. If you want to predict -- I'm sorry.</p> <p>12 Q. Yeah. And then you can apply it to the</p> <p>13 phase model, right?</p> <p>14 A. No.</p> <p>15 MS. SCOTT: Objection.</p> <p>16 A. Well, There's multiple ways of predicting</p> <p>17 what a deposit would be, and it's scale dependent, phase</p> <p>18 dependent. It's dependent on the geology, and it's</p> <p>19 dependent upon tectonics, as well. So there's many</p> <p>20 things. So as a mineralogist, you know, one thing that</p> <p>21 I would heavily rely on are the phase diagrams.</p> <p>22 BY MR. FROST:</p> <p>23 Q. Sure. But you have to know the specific</p> <p>24 history of a formation if you want to do an accurate</p> <p>25 prediction of what's in that particular thing. The</p>	<p style="text-align: right;">Page 140</p> <p>1 BY MR. FROST:</p> <p>2 Q. Then you cite Evans 2004 as the basis for</p> <p>3 that statement?</p> <p>4 A. Yes.</p> <p>5 MR. FROST: Let's mark this.</p> <p>6 MR. LAPINSKI: What number is this?</p> <p>7 VIDEOGRAPHER: Nine.</p> <p>8 MR. FROST: I told you I'd forget.</p> <p>9 (Exhibit 9 was marked for</p> <p>10 identification.)</p> <p>11 BY MR. FROST:</p> <p>12 Q. Do you recognize this article?</p> <p>13 A. Yes, I do.</p> <p>14 Q. Can you point to me where this article</p> <p>15 shows that talc and chrysotile are associated with each</p> <p>16 other in deposits?</p> <p>17 A. The thing I was referring to is</p> <p>18 concluding remarks. "Despite an up temperature</p> <p>19 transition from lizardite to chrysotile at these</p> <p>20 temperatures, the latter remains metastable."</p> <p>21 So basically in giving these diagrams,</p> <p>22 the thermodynamic diagrams, because that metastability,</p> <p>23 that's the kinetic thing, that's what, essentially, the</p> <p>24 chrysotile would potentially persist.</p> <p>25 Q. Okay. So he's not saying that. You're</p>
<p style="text-align: right;">Page 139</p> <p>1 phase diagrams are one of the things you'd look at,</p> <p>2 right?</p> <p>3 MS. SCOTT: Objection.</p> <p>4 A. You would use phase diagrams to predict</p> <p>5 potential, potentially what would be in text, because</p> <p>6 you have this kinetic issue, right.</p> <p>7 BY MR. FROST:</p> <p>8 Q. Yeah, and that's based upon the geologic</p> <p>9 formation, all the other factors that come into how that</p> <p>10 formation was formed, temperature, pressure, time, you</p> <p>11 know, all the things that we've talked about, right?</p> <p>12 A. You can use the phase diagrams. Also if</p> <p>13 you have bulk chemistry data -- if you have bulk</p> <p>14 chemistry data, you can use that bulk chemistry data,</p> <p>15 sort of figure out and do models to see where things</p> <p>16 are. So you don't necessarily have to know -- so you</p> <p>17 can, you an model things, and that model would give you</p> <p>18 some prediction.</p> <p>19 Q. If you look at the next sentence, it</p> <p>20 says, "Talc and chrysotile are associated with each in</p> <p>21 talc deposits at the micrometer and nanometer scale</p> <p>22 making the separation impossible during the mining and</p> <p>23 manufacturing process." Do you see that?</p> <p>24 A. Yes.</p> <p>25</p>	<p style="text-align: right;">Page 141</p> <p>1 just interpreting that from this article? That's not</p> <p>2 his conclusion? That's yours?</p> <p>3 A. That is the interpretation of the</p> <p>4 thermodynamic, you know, this article. And I think that</p> <p>5 data supports it as does other, you know, these</p> <p>6 diagrams.</p> <p>7 Q. What I'm saying is that's not his.</p> <p>8 That's not Evans' conclusion. That's you interpreting</p> <p>9 data within the Evans report, correct?</p> <p>10 MS. SCOTT: Objection.</p> <p>11 A. Yes, but I'm citing that.</p> <p>12 BY MR. FROST:</p> <p>13 Q. Okay. Let's move on. The next</p> <p>14 paragraph, the one that starts "Metamorphic systems." I</p> <p>15 believe it's the last sentence. It says, "Reactions can</p> <p>16 also progress for some period and then revert to</p> <p>17 asbestiform mineral chrysotile," and it continues</p> <p>18 because it changes.</p> <p>19 So, hopefully, you'll agree with me on</p> <p>20 this one. For it to revert back to chrysotile, it would</p> <p>21 have to have started as chrysotile, correct?</p> <p>22 A. So that is a possibility. You can go</p> <p>23 from -- that's what the stability fields are all about.</p> <p>24 So you can start off as chrysotile. You can cross that</p> <p>25 phase boundary, and then it can revert back if the</p>

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<p style="text-align: right;">Page 142</p> <p>1 conditions change back. And, actually, we know this in 2 metamorphic rocks, that, essentially, the phase 3 assemblage can basically go back and forth, back and -- 4 it can revert. So I'm specifically -- I'm talking about 5 reverting on that phase boundary. 6 Q. Yes, but it can only revert back to 7 chrysotile if it started at chrysotile, right? 8 A. So that might be a poor phrasing of the 9 word, but essentially it's not an inaccurate phrasing. 10 So when I wrote this, I was thinking of these phase 11 diagrams. 12 Q. What I'm getting at is, let's say it 13 started as, you know, a serpentinite or an anthophyllite 14 converted to talc. It's not going to then revert back 15 to a different crystal, right? It's not going to -- 16 it's not going to go from anthophyllite to talc to 17 chrysotile? 18 A. Based on the geologic history, there's 19 multiple pathways. So it won't revert to the same magic 20 crystal, if that's what you're implying. 21 Q. So the way -- and I agree with you. It's 22 very inartfully written here. So you say, "Reactions 23 can progress for some period of time and then revert to 24 the mineral chrysotile." So the reactions of talc can 25 only revert back to chrysotile if that's where they</p>	<p style="text-align: right;">Page 144</p> <p>1 completely new chemical structure of chrysotile, 2 correct? 3 A. Correct. Not all the time, yeah. 4 Q. Okay. Thank you. Bear with me a second 5 here. Okay. Next paragraph down after you cite the 6 various Imerys documents, you said, "A 1977 thesis by 7 Barry Seymour (JNJ 272469) describes the complex 8 mineralogical development of the specific ore." So are 9 you talking about the specific ore in the Seymour paper 10 or are you talking about the specific ore at issue in 11 this case? 12 A. I forget. Can we bring that document up? 13 Q. Yeah, I can get you Seymour. 14 MR. FROST: Would you like a copy? 15 MS. SCOTT: Yes, please. Thank you. 16 (Exhibit 10 was marked for 17 identification.) 18 MS. SCOTT: Are you marking this? 19 MR. FROST: Yes, I forget what number it 20 is. 21 MS. SCOTT: Ten. 22 MR. FROST: Ten. 23 A. I think "specific" is -- I think it might 24 be a typo. 25</p>
<p style="text-align: right;">Page 143</p> <p>1 started from, correct? 2 MS. O'DELL: Objection to form. 3 A. So let me just read the sentence before 4 here, because I think -- "Reactions may also be 5 incomplete, meaning there may not be enough geologic 6 time or other chemical component to drive the reaction 7 to completion as discussed in Deer, Howie and Zussman. 8 Reactions can also progress for some period of time, 9 then revert to asbestiform mineral chrysotile because of 10 changes in geologic conditions." 11 So, in part, I think I'm referring to 12 Deer, Howie and Zussman. I don't think I've said 13 anything inaccurate there. It's not exclusive to -- 14 BY MR. FROST: 15 Q. I'm trying to clarify -- 16 A. You know, you can have reactions, you 17 know, that's not complete. 18 Q. So what I'm getting at, it's a really 19 simple question. The reversion won't always be from 20 talc to chrysotile, right? It will only revert back to 21 chrysotile if that's where it started. Do you agree 22 with me there? So while it may be correct that if it 23 starts as chrysotile, partially transforms to talc and 24 reverts back to chrysotile, that makes sense. But if it 25 starts as something else, it's not going to revert to a</p>	<p style="text-align: right;">Page 145</p> <p>1 BY MR. FROST: 2 Q. Okay. 3 A. So as I look at this document, I 4 basically remember looking at the introductory material 5 in it. So -- 6 Q. You'd agree with me it's a thesis about 7 the East Johnson mine? 8 A. I would have to reread the document. 9 Q. If I would represent to you it's about 10 the East Johnson mine and if you actually look at the 11 abstract -- 12 A. Foley and Johnson. 13 Q. And you'd also agree with me the East 14 Johnson mine was never one that was used for cosmetic 15 talcum powder by Johnson & Johnson, correct? 16 MS. O'DELL: Objection to form. 17 A. It may not have been used, but it is in 18 the same general geology. And, certainly, in geology, 19 it is part of the same general terrane, so therefore, 20 it's not exactly like the hammer, the Rainbow mine, but 21 it is relevant because it's geologically connected in 22 the sense of the terranes. 23 BY MR. FROST: 24 Q. So you're telling me that it has the same 25 formation as the deposits in the Hammondsville and</p>

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<p>1 Rainbow mines or are you just saying --</p> <p>2 A. I don't remember specifically, but</p> <p>3 essentially the geology, so...</p> <p>4 Q. The second half of my question, or is it</p> <p>5 more that you're basing it on they're all part of the</p> <p>6 ultramafic belt, the Appalachian ultramafic belt that</p> <p>7 runs from Quebec through Georgia?</p> <p>8 A. It is more the general geologic</p> <p>9 association.</p> <p>10 Q. Okay. That's all I was going to ask</p> <p>11 about that.</p> <p>12 A. Page 15 is geologic map of Vermont. It</p> <p>13 shows things being connected.</p> <p>14 Q. Well, it shows the Appalachian ultramafic</p> <p>15 belt running through Vermont, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Turn to page 6 of your report, the</p> <p>18 "Common toxic metals of interest." So before we start</p> <p>19 looking at any specific documents, will you agree with</p> <p>20 me that seeing metals at certain levels in deposit</p> <p>21 samples is different than seeing metals in certain</p> <p>22 levels in a finished talcum powder product?</p> <p>23 MS. SCOTT: Objection.</p> <p>24 A. It can be metals in processing. It could</p> <p>25 be reduced or they could also be increased depending</p>	<p>1 define the geology as a whole, you know. So they want</p> <p>2 to know where ore is and where ore is not, if there is</p> <p>3 problematic areas. So, for example, the mine I work</p> <p>4 with in Nevada, they have a formation, Stebbins Hill</p> <p>5 unit that they avoid, because it's got all kinds of</p> <p>6 problematic stuff in it.</p> <p>7 Q. And that's probably a pretty good</p> <p>8 example. I take it they -- every now and again, they</p> <p>9 take samples from the problematic portion of that mine,</p> <p>10 correct?</p> <p>11 A. They sample everything as they go. So</p> <p>12 I've seen datasets of 20,000 from a single -- single</p> <p>13 level.</p> <p>14 Q. So what I'm getting to is just because</p> <p>15 you have a test of -- you know, a test coming back from</p> <p>16 a mine doesn't necessarily mean that the rock associated</p> <p>17 with that test makes it into the final product, right?</p> <p>18 MS. SCOTT: Objection.</p> <p>19 A. I don't -- there's no -- I didn't see any</p> <p>20 specific chain of custody, so I can't, you know.</p> <p>21 BY MR. FROST:</p> <p>22 Q. I'm talking from a general perspective.</p> <p>23 They're sampling a lot more of the rock than that</p> <p>24 ultimately ends up in a final product in a mine,</p> <p>25 correct?</p>
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<p>1 upon the details of the processing. I don't think I saw</p> <p>2 any documents, although I requested documents, any</p> <p>3 documents about the detail, you know, before -- before</p> <p>4 and after, kind of full throughput, you know, as far as</p> <p>5 watching a specific sample go through, but, yeah.</p> <p>6 BY MR. FROST:</p> <p>7 Q. You'd also agree with me, too, that</p> <p>8 sometimes mine samples aren't necessarily from the ore</p> <p>9 that is used in the final product. It might be from a</p> <p>10 boundary. It might be from a surrounding rock, a black</p> <p>11 wall. Just because you see something in a sample</p> <p>12 doesn't necessarily mean that that's the ore that is</p> <p>13 then converted over into the final powder as well,</p> <p>14 correct?</p> <p>15 MS. SCOTT: Objection.</p> <p>16 MS. O'DELL: Object to form.</p> <p>17 A. I am confused by the question. As I</p> <p>18 think I understand you, can contaminants or other</p> <p>19 material that is not the primary ore be included in the</p> <p>20 ore processing?</p> <p>21 BY MR. FROST:</p> <p>22 Q. Other way around. When you sample a</p> <p>23 mine, when you drill sample holes, they're not just</p> <p>24 drilling the mineable ore body, correct?</p> <p>25 A. Generally correct. They're looking to</p>	<p>1 MS. SCOTT: Objection.</p> <p>2 A. So there's a difference between coring to</p> <p>3 define your geology and then mining --</p> <p>4 BY MR. FROST:</p> <p>5 Q. Uh-huh. That's what I'm saying.</p> <p>6 A. -- to get your product.</p> <p>7 Q. So just because you find something here</p> <p>8 doesn't necessarily mean that that ends up, that</p> <p>9 particular test sample ends up in the final ore that</p> <p>10 makes it to the grinding process for final talc,</p> <p>11 correct?</p> <p>12 MS. SCOTT: Objection. Speculation.</p> <p>13 A. Yeah. You don't -- that would be</p> <p>14 speculative or you -- it doesn't mean it doesn't.</p> <p>15 BY MR. FROST:</p> <p>16 Q. But, again, that's why --</p> <p>17 A. So --</p> <p>18 Q. Okay. I'll ask you this way. Does every</p> <p>19 single sample that's ever tested in a mine --</p> <p>20 MS. O'DELL: Excuse me. You guys just --</p> <p>21 MR. FROST: Sure.</p> <p>22 MS. O'DELL: If you'd give him a chance</p> <p>23 to finish.</p> <p>24 MR. FROST: I thought he did finish his</p> <p>25 question.</p>

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<p>1 MS. O'DELL: I don't think he did. I'm</p> <p>2 sure he needs to give you an opportunity to</p> <p>3 finish as well --</p> <p>4 MR. FROST: I'm sorry. I thought you had</p> <p>5 finished your question.</p> <p>6 MS. O'DELL: But you're talking over each</p> <p>7 other. In fact, you just interrupted me.</p> <p>8 A. That's why I was distracted. Can you</p> <p>9 restate your question again, please?</p> <p>10 BY MR. FROST:</p> <p>11 Q. Sure. So my question is: Every sample</p> <p>12 that comes out of a mine doesn't -- you know, everywhere</p> <p>13 they're sampling, they're doing core outside of the talc</p> <p>14 body. They're coring through. They're trying to find</p> <p>15 areas of ore they don't use. Do you agree with all</p> <p>16 these as just general mining concepts?</p> <p>17 A. Generally.</p> <p>18 Q. Okay.</p> <p>19 A. But it -- go ahead.</p> <p>20 Q. And you also agree with me that,</p> <p>21 generally, mines aren't just sampling from the ore they</p> <p>22 are using to put into a final product, correct?</p> <p>23 MS. SCOTT: Objection.</p> <p>24 A. Correct. But that doesn't mean that --</p> <p>25 that doesn't mean that you're not, when you sample and</p>	<p>1 hypothetical questions here. I'm trying to get down to,</p> <p>2 and again, as part of the mining process, you sample to</p> <p>3 determine which parts of the ore you avoid and which</p> <p>4 parts of the ore you mine, right?</p> <p>5 A. Yes. That is a common procedure.</p> <p>6 Q. So just because a sample comes up and has</p> <p>7 a hit of a particular chemical in it doesn't necessarily</p> <p>8 mean that they then use that as a final product, because</p> <p>9 part of sampling is to tell you what parts of the mine</p> <p>10 to avoid, right?</p> <p>11 MS. SCOTT: Objection.</p> <p>12 A. Potentially. But there's reasonable</p> <p>13 risk. If you find it in one spot, it might be near</p> <p>14 another spot. When you have high concentrations, such</p> <p>15 as those observed, it's a natural. Essentially, you</p> <p>16 have gradients that occur over some degree of space. So</p> <p>17 you, you know, so arsenic might have, you know, a</p> <p>18 thousand parts per million in one spot and be zero in</p> <p>19 another, but without, you don't know where to mine,</p> <p>20 where that's cut -- cut off.</p> <p>21 BY MR. FROST:</p> <p>22 Q. But, again, but my question's very easy,</p> <p>23 and it's just because you see something here doesn't</p> <p>24 mean it's there, right? You'd have to know more?</p> <p>25 MS. SCOTT: Objection.</p>
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<p>1 find things like asbestos, it doesn't negate that they</p> <p>2 exist.</p> <p>3 BY MR. FROST:</p> <p>4 Q. Okay. Here's my next question: Based on</p> <p>5 that, just because a sample comes back with a particular</p> <p>6 level of some, say, heavy metal, you know, just because</p> <p>7 some sample in a mine somewhere came up with a level of</p> <p>8 chromium, for example, based on that sample, you can't</p> <p>9 say, without knowing more, that that particular area</p> <p>10 where the sample came from ultimately ended up in talcum</p> <p>11 powder that consumers used, right?</p> <p>12 MS. SCOTT: Objection. Calls for</p> <p>13 speculation.</p> <p>14 A. So, yeah, I think it is speculative,</p> <p>15 because you're talking about one powder. There's many,</p> <p>16 many analyses of things. So you're not -- you're not</p> <p>17 gonna spend a huge amount of time on things that are not</p> <p>18 directly related to your work, because, you know, you do</p> <p>19 have to keep costs in mind. So, you know, if -- you</p> <p>20 know, there were numerous, numerous, numerous analyses</p> <p>21 of arsenic, for example, in some of the Vermont</p> <p>22 material. So, you know, some of those were related to</p> <p>23 ores. And let's look to --</p> <p>24 BY MR. FROST:</p> <p>25 Q. We don't need to. I'm asking very just</p>	<p>1 BY MR. FROST:</p> <p>2 Q. Right?</p> <p>3 A. Correct.</p> <p>4 Q. Okay. And just because something shows</p> <p>5 up here doesn't necessarily mean it's going to end up in</p> <p>6 what becomes the mill feed, right?</p> <p>7 MS. SCOTT: Objection.</p> <p>8 A. Correct. But there's always the</p> <p>9 potential for it to do so.</p> <p>10 BY MR. FROST:</p> <p>11 Q. Okay. And you also agree with me that</p> <p>12 beneficiation is one way that mines specifically for</p> <p>13 talc can clean out some of the accessory minerals and</p> <p>14 some of the heavy metals, right?</p> <p>15 MS. O'DELL: Object to the form.</p> <p>16 A. Beneficiation works when applied</p> <p>17 properly. I'm not a mineral engineer, so I don't fully</p> <p>18 think I can comment on details of that.</p> <p>19 BY MR. FROST:</p> <p>20 Q. Okay. But you agree with me that</p> <p>21 beneficiation is one way in which you can reduce the</p> <p>22 amount of, say, a heavy metal that ends up in a final</p> <p>23 product, correct?</p> <p>24 MS. SCOTT: Objection.</p> <p>25 A. I would rather not comment, so the --</p>

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<p style="text-align: right;">Page 154</p> <p>1 BY MR. FROST: 2 Q. You comment in your report specifically 3 about the beneficiation going on at the Vermont mines. 4 So is that not something you're going to opine on here? 5 MS. SCOTT: Do you want to point him to 6 the place in his report? 7 A. Yeah. Sorry. Is this the Colorado mines 8 study? 9 BY MR. FROST: 10 Q. Yeah, it might be. I don't have it right 11 in front of me. It's something that I think we can get 12 back to later. But you agree with me as a general 13 mining concept -- 14 A. I'd like to see the document. 15 Q. Yeah. Well, I'm asking you general 16 concepts, because you are giving opinions about the 17 mining that was going on at these mines, correct? 18 A. Yes. 19 Q. And beneficiation is one thing that mines 20 use, correct? 21 A. Yes. 22 Q. And beneficiation can be used to reduce 23 the amount of contaminants that are in an ore, correct? 24 MS. SCOTT: Objection. 25 MS. O'DELL: Objection to form.</p>	<p style="text-align: right;">Page 156</p> <p>1 beforehand, and basically, they walked away with \$50,000 2 worth of aquamarines. So gem mining certainly is 3 something that you could selectively mine. 4 Gold is another example where there are 5 deposits in Nigeria where, essentially, groups of women 6 go out and they selectively, you know, go through, 7 basically pan and find gold nuggets. I think it's -- 8 you know, it really depends on how you say selective 9 mining, and so the thing that, you know -- did I answer 10 that? 11 Q. I'm listening to your explanation, yeah. 12 A. Okay. So selective mining, I think in 13 the context of talc deposits, is -- I really don't think 14 you can effectively do it. So with respect to Chinese 15 ore that is supposedly hand sorted -- let me find where 16 that section is. So if you're -- yeah, as I understand 17 it, they basically look at the rock and say it's okay. 18 There's nothing wrong. 19 Well, there's several issues with that. 20 So, one, the human eye cannot detect either metals or 21 small asbestos fibers by simply looking at, at the rock, 22 at the surface of the rock, right? So, essentially, you 23 can do it. You can visually inspect the outside of the 24 material, and you would not be able to visibly see if 25 there's a thousand parts per million of nickel or</p>
<p style="text-align: right;">Page 155</p> <p>1 A. Reduce, but not purify. 2 BY MR. FROST: 3 Q. It can be used to reduce, correct? 4 MS. SCOTT: Objection. 5 A. Potentially, if executed well. 6 BY MR. FROST: 7 Q. Okay. And selective mining is another 8 tactic that can be used in an ore to try to reduce 9 contaminates, correct? 10 MS. SCOTT: Objection. 11 A. No. There's -- the selective mining was 12 an issue, significant issue that I found. And the 13 reason -- 14 BY MR. FROST: 15 Q. I'm asking in general, sir. Can 16 selective mining -- 17 A. In general, I don't -- you know, I think 18 it really depends on what you mean by "selective 19 mining." So I think a good effective example of 20 selective mining would be gemstones. So you find a 21 pegmatite. You go -- actually, there was a group that 22 did this a couple years ago. They went to a site in 23 Colorado. They basically looked at the geology. They 24 selectively looked at specific lithologies. They were 25 able to narrow it down. They did a lot of research</p>	<p style="text-align: right;">Page 157</p> <p>1 chromium or some other element. 2 And then, in addition, you can have 3 inclusions of stuff in the rock that you could not -- 4 you just physically can't see. So there's a 5 hypothetical risk that you can have inclusion of, let's 6 say, sulfides, a lot of sulfides, a nodule that has a 7 lot of sulfides in it, that, in this chunk, you would 8 not be able to visually discern what was there. So and 9 then, you know, so you basically -- and so that's the 10 sorting, as I understand it, with China. 11 Q. Do you agree with me that -- so, is it 12 your opinion that selective mining for talc can never 13 work or do you agree with me that selective mining is 14 one of the tools that a mine can use to help to purify 15 its ore? 16 A. I would say in the context of -- in the 17 context of talc, selective mining is not very effective, 18 because the scale of the issue is with the ore. 19 Q. Okay. Other than your personal opinion, 20 can you cite to me any peer-reviewed or scientific 21 source that supports that? 22 MS. SCOTT: Objection. 23 A. I don't think there's any peer-reviewed 24 literature that I can think of. I think it's just 25 common sense. You know, everyone knows that you can</p>

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<p>1 hide -- you can have inclusions and impurities in an 2 ore. And if you're only using your eyes and you're only 3 hand sorting things -- plus there's human error. 4 There's just simply human error. If someone, you know, 5 is, you know -- they'll just make mistakes. 6 And then the other issue I think is 7 unclear, I didn't find any degree of training, you know, 8 or no description of the training methods that were used 9 for hand sorting. So an ore-controlled geologist is a 10 common, common position in mines. 11 One of my former students, he's an 12 ore-controlled geologist in Stillwater, and it takes 13 three months of training for them to delineate the ore. 14 So that is an example of selective mining, but there's a 15 high level of effort that goes into it, and the goal is 16 platinum. And, basically, the way that particular mine 17 is set up is to extract the platinum. They're not 18 really -- they don't have to worry about other 19 contaminants that might be present. 20 BY MR. FROST: 21 Q. Okay. I'm going to stop you because we 22 keep getting off on a lot of these tangents. My 23 question was: Can you point me to any mining studies or 24 anything else that say that selective mining does not 25 work for talc?</p>	<p>1 basis of this is Van Gosen 2004. I'm going to mark 2 that. 3 A. Okay. It's the environmental earth 4 science paper? 5 Q. What's that? 6 A. It's the environmental earth science 7 paper? It's the journal? 8 Q. Yes. Environmental Geology, 2004. 9 A. Oh, yeah. That's currently -- the 10 journal name changed. I had a few papers in it. Is 11 there a copy of it? 12 Q. The court reporter's marking it. 13 (Exhibit 11 was marked for 14 identification.) 15 BY MR. FROST: 16 Q. Since we've already established we're 17 talking about the same paper, can you show me anywhere 18 in this paper that Van Gosen specifically speaks about 19 any of the mines that you've listed here in your report? 20 A. Correct. No specific mine is listed. It 21 talks about Vermont talc, in general. 22 (Exhibit 12 was marked for 23 identification.) 24 BY MR. FROST: 25 Q. I've now marked the Ross article. It's</p>
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<p>1 A. I know of no peer-review publications. 2 Q. Okay. Thank you. Turn to page 7 of your 3 report. It's 7 into 8, actually. You know, we start 4 talking about the various regions that talc is sourced 5 from, correct? 6 A. Yes. 7 Q. Okay. On page 7 to 8, you list various 8 time frames and various mines, you know, from which you 9 believe. I take it this came from your review of the 10 documents, the timeline that you put forth here? 11 A. Just give me a moment to review. 12 Q. The easier way to ask is: Is this 13 something that was provided to you or is this something 14 that you came up with yourself? 15 A. I came up with it. 16 Q. Okay. So at the very end of it, so we 17 talked about all the various mines, and afterwards, you 18 have a sentence that reads, "These mines are known to 19 have impurities associated with talc, including toxic 20 metals, chrysotile, and amphibole asbestos." Do you see 21 that? 22 MS. O'DELL: Objection to form. 23 A. Yes. 24 BY MR. FROST: 25 Q. Okay. So the first thing you note as the</p>	<p>1 Ross 74. "Environmental Health Perspectives." She's 2 already marked it for you. 3 A. Oh. 4 Q. Same question. Can you show me where in 5 this article it details any mine actually used by 6 Johnson & Johnson? 7 MS. SCOTT: Objection. 8 A. I don't see mention of a specific mine. 9 BY MR. FROST: 10 Q. Next, I'm going to mark -- I'm sorry. 11 A. Go ahead. 12 Q. I didn't mean to cut you off if you 13 weren't done. Next I'm going to mark Document 14 JNJ 000521616, the first page of it, anyway. 15 (Exhibit 13 was marked for 16 identification.) 17 BY MR. FROST: 18 Q. Do you remember looking at this document? 19 A. Actually, I'm unsure. 20 Q. Okay. 21 A. I might have used the wrong number. 22 Q. Okay. But you agree with me this doesn't 23 talk about any of the mines, certainly, right? 24 A. Right. Yeah. 25 MS. SCOTT: Object to form.</p>

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<p>1 MS. O'DELL: Object to form.</p> <p>2 A. Correct. I -- I haven't -- I don't think</p> <p>3 I've seen this. I think I used -- there's a typo or</p> <p>4 something in there. Sorry.</p> <p>5 BY MR. FROST:</p> <p>6 Q. No. That's okay. That's why we're --</p> <p>7 that's why we're doing this.</p> <p>8 All right. If you turn to page 14 of</p> <p>9 your report under, "Evidence that Asbestos Occurred in</p> <p>10 Defendants' Mines." The first sentence reads, "The</p> <p>11 documents I reviewed provided strong evidence that the</p> <p>12 talc used by Imerys and Johnson & Johnson to produce</p> <p>13 Johnson's Baby Powder and Shower to Shower came from</p> <p>14 mines that contained asbestos minerals or fibrous talcum</p> <p>15 in an asbestiform habit." Did I read that right?</p> <p>16 A. Yes.</p> <p>17 Q. And looking back, you cite the same exact</p> <p>18 documents as we just -- as the last sentence, correct?</p> <p>19 MS. SCOTT: Objection.</p> <p>20 A. It's in the report.</p> <p>21 BY MR. FROST:</p> <p>22 Q. Yeah. Okay. And you'd agree with me,</p> <p>23 you know, that these materials don't actually relate</p> <p>24 directly to the mines used by Johnson & Johnson as</p> <p>25 identified on pages -- I believe it's 7 and 8 of your</p>	<p>1 as amphibole and grit and stuff like that, correct?</p> <p>2 A. So, for example, the one ending in 87231,</p> <p>3 "Battelle Memorial Institute document dated 1958,</p> <p>4 indicated the presence of tremolite in the talc,</p> <p>5 commonly at levels ranging from 1-3 percent. That</p> <p>6 document also studied the abrasiveness and grit of</p> <p>7 Italian talc." So that's something, that the grit is in</p> <p>8 addition to the finding of tremolite.</p> <p>9 Q. Do you agree with me that none of these</p> <p>10 documents actually find asbestos or define that they</p> <p>11 have found asbestos in any of the ore from Italy?</p> <p>12 MS. O'DELL: Object to the form.</p> <p>13 A. I would want to double-check all of</p> <p>14 these, but they do two things. The last one, presence</p> <p>15 of tremolite and actinolite and, also, tremolite and one</p> <p>16 that I just mentioned. And tremolite is a -- recognized</p> <p>17 as a carcinogen by IARC 2012.</p> <p>18 Q. Can you show me anywhere in your report</p> <p>19 that you note that tremolite is found by IARC to be a</p> <p>20 potentially dangerous mineral, you know, a human</p> <p>21 carcinogen?</p> <p>22 (Exhibit 14 was marked for</p> <p>23 identification.)</p> <p>24 A. I can't find a specific example.</p> <p>25</p>
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<p>1 report, right?</p> <p>2 MS. SCOTT: Objection.</p> <p>3 MS. O'DELL: Objection to form.</p> <p>4 A. I would have to read -- double -- I would</p> <p>5 want to double-check each individual document.</p> <p>6 BY MR. FROST:</p> <p>7 Q. But, certainly, the ones we just looked</p> <p>8 at --</p> <p>9 A. The one we just looked at.</p> <p>10 Q. -- certainly don't support that, right?</p> <p>11 A. Correct.</p> <p>12 Q. Okay. All right. Move on to the next</p> <p>13 section of the report. It's "Mines in Italy," pages 8</p> <p>14 to 9, I believe, of your report.</p> <p>15 A. Oh, 8 to 9.</p> <p>16 Q. Then on page 9, it's the third paragraph.</p> <p>17 You have, "Based on what I have reviewed, I have</p> <p>18 sufficient basis to conclude that Italian ore was of</p> <p>19 poor quality," correct?</p> <p>20 A. Yes.</p> <p>21 Q. What are you talking about there when you</p> <p>22 say "poor quality"?</p> <p>23 A. That I'm referring to the findings of the</p> <p>24 items listed below.</p> <p>25 Q. These items are talking about things such</p>	<p>1 BY MR. FROST:</p> <p>2 Q. And you're not qualified to say whether</p> <p>3 or not a particular mineral would be harmful, you know,</p> <p>4 as a human carcinogen. You have no basis by which to</p> <p>5 say that's correct or not correct, right?</p> <p>6 MS. SCOTT: Objection.</p> <p>7 A. Correct. I'm not a medical.</p> <p>8 BY MR. FROST:</p> <p>9 Q. Okay. All right. What number was that?</p> <p>10 Fourteen. So I've just marked -- I've given you a</p> <p>11 binder marked 14. It has tabs 1 through 5. I'm sorry.</p> <p>12 I have yours. I apologize.</p> <p>13 So these are the various documents you</p> <p>14 cite in your report. So let's look through each of</p> <p>15 them. We'll start with 1.</p> <p>16 MS. O'DELL: Let's get this one back</p> <p>17 together.</p> <p>18 MR. FROST: Oh, did it come apart?</p> <p>19 MS. O'DELL: Yes. Is there a particular</p> <p>20 part of his report that these came from or are</p> <p>21 you jumping around?</p> <p>22 MR. FROST: Yes. No, we're talking about</p> <p>23 the report now. They're page 9 to 10. These</p> <p>24 are the documents that support the</p> <p>25 ore-is-of-poor-quality statement.</p>

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<p style="text-align: right;">Page 166</p> <p>1 BY MR. FROST:</p> <p>2 Q. So this first one, can you tell me</p> <p>3 anywhere in the Battelle report that starts JNJ 87868,</p> <p>4 that they note the trace amounts of amphibole are</p> <p>5 asbestiform in any way?</p> <p>6 MS. O'DELL: Object to the form.</p> <p>7 A. No, I don't.</p> <p>8 BY MR. FROST:</p> <p>9 Q. Okay. Turn to tab 2, which is -- the</p> <p>10 document starts JNJ 87231. Same question. Can you tell</p> <p>11 me anywhere in here where, I believe it's Battelle</p> <p>12 again, identifies finding any asbestiform mineral?</p> <p>13 MS. SCOTT: Objection.</p> <p>14 A. So tremolite is noted as trace on page 4</p> <p>15 here.</p> <p>16 BY MR. FROST:</p> <p>17 Q. Does it note the trace tremolite has</p> <p>18 asbestiform?</p> <p>19 A. No, it does not.</p> <p>20 Q. So you'd have no way to tell whether or</p> <p>21 not it's asbestiform or non-asbestiform based on this</p> <p>22 document?</p> <p>23 MS. O'DELL: Object to form.</p> <p>24 MS. SCOTT: Objection.</p> <p>25 A. The -- it has been so, "The amphibole</p>	<p style="text-align: right;">Page 168</p> <p>1 BY MR. FROST:</p> <p>2 Q. But it's JNJAZ55_6104. I think it starts</p> <p>3 at 6103, but 6104 is the letter. The one, two, three --</p> <p>4 fourth paragraph down says, "I have also checked into</p> <p>5 the mineralization of that part of the territory, and</p> <p>6 the minerals which show in the valley are: Talc,</p> <p>7 pyrite," magnesite -- sorry, "magnetite, calcite,</p> <p>8 dolomite, apatite, clinocllore," sorry, "chrysotile,"</p> <p>9 and then, you know, talks about others, including</p> <p>10 tremolite, actinolite, correct?</p> <p>11 A. Yes.</p> <p>12 Q. And this is talking about the valley.</p> <p>13 There is nothing in here that indicates that this is</p> <p>14 talking specifically about the Fontaine mine, correct?</p> <p>15 MS. SCOTT: Objection.</p> <p>16 MS. O'DELL: Objection.</p> <p>17 A. It's unclear.</p> <p>18 BY MR. FROST:</p> <p>19 Q. Dr. Ashton also isn't saying that any of</p> <p>20 these minerals have been found in the ore coming from</p> <p>21 the Fontaine mine, correct?</p> <p>22 MS. O'DELL: Objection to form.</p> <p>23 MS. SCOTT: Objection.</p> <p>24 A. Correct, but mineralization of that part</p> <p>25 of the territory. So...</p>
<p style="text-align: right;">Page 167</p> <p>1 component has been established to be the variety of</p> <p>2 tremolite." Yeah. It does not say that it is asbestos</p> <p>3 form, but it is tremolite.</p> <p>4 BY MR. FROST:</p> <p>5 Q. Okay. Turn to tab 17 -- or sorry, tab 3.</p> <p>6 It's the document Bates numbered JNJAZ55_213.</p> <p>7 And, again, I think it mentions tremolite</p> <p>8 and actinolite as things that may be in the ore, but it</p> <p>9 doesn't talk about whether or not anything's asbestiform</p> <p>10 or any levels, correct?</p> <p>11 A. True. It does say tremolite and</p> <p>12 actinolite.</p> <p>13 Q. Turn to tab 4. Somebody's conveniently</p> <p>14 put an arrow, I think, to the paragraph that you're</p> <p>15 relying on. It states -- sorry, this is the document</p> <p>16 that starts JNJAZ --</p> <p>17 MS. O'DELL: Just to make clear --</p> <p>18 MR. FROST: It's on the document.</p> <p>19 MS. O'DELL: It's the original.</p> <p>20 MR. FROST: Yeah. I was going to say,</p> <p>21 it's not something we've done.</p> <p>22 MS. SCOTT: Or anyone else?</p> <p>23 MR. FROST: Yes. It's part of the</p> <p>24 original document as produced.</p> <p>25</p>	<p style="text-align: right;">Page 169</p> <p>1 BY MR. FROST:</p> <p>2 Q. But there can be different mineral</p> <p>3 profiles throughout the valley depending on when it</p> <p>4 formed, what it formed from?</p> <p>5 A. Yes, and it could be present because of</p> <p>6 the association observed.</p> <p>7 Q. Unfortunately, there's just no way to</p> <p>8 tell from this document, correct?</p> <p>9 MS. SCOTT: Objection.</p> <p>10 MS. O'DELL: Object to form.</p> <p>11 A. Correct.</p> <p>12 BY MR. FROST:</p> <p>13 Q. All right. Turn to tab 5. It's the</p> <p>14 document that starts JNJAZ_87. This is the Pooley</p> <p>15 report from 1972. It's very long, so I'll help you out.</p> <p>16 If you turn to the very end of it --</p> <p>17 MS. O'DELL: Doctor, feel free to --</p> <p>18 BY MR. FROST:</p> <p>19 Q. Yeah. I was going to say, you can review</p> <p>20 the whole thing if you want, but I'm going to</p> <p>21 concentrate on the "Conclusions" section.</p> <p>22 If you look at -- it's on page 121 of the</p> <p>23 report.</p> <p>24 A. Oh, this one.</p> <p>25 Q. Do you recognize that you've seen this</p>

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<p style="text-align: right;">Page 170</p> <p>1 one?</p> <p>2 A. Yeah.</p> <p>3 Q. The quality's bad.</p> <p>4 A. Oh, there's -- you can see chrysotile.</p> <p>5 "Examples of commercial amphibole and chrysotile</p> <p>6 asbestos particles together with typical selected area</p> <p>7 electron diffraction patterns." Yeah. So the images</p> <p>8 are here, but, yeah. So, yeah. That's right. That</p> <p>9 page you can't tell.</p> <p>10 MS. O'DELL: What page are you on?</p> <p>11 THE WITNESS: I'm on Page 56. I'm sorry.</p> <p>12 MS. O'DELL: Yeah. No, no. I'm just</p> <p>13 trying to follow along. You go where you need</p> <p>14 to go.</p> <p>15 A. Amosite asbestos particles there.</p> <p>16 BY MR. FROST:</p> <p>17 Q. Again, the chrysotile you pointed out on</p> <p>18 56, he's showing you an example of what a commercial</p> <p>19 chrysotile looks like, right, not a picture of what came</p> <p>20 from the talc. Do you agree?</p> <p>21 MS. O'DELL: Object to the form.</p> <p>22 A. What's your question?</p> <p>23 BY MR. FROST:</p> <p>24 Q. When you just talked about 56, the</p> <p>25 picture of chrysotile you're talking about is a</p>	<p style="text-align: right;">Page 172</p> <p>1 formed from the amphibole mineral found at the mine were</p> <p>2 hardly fibrous in character, the majority of the</p> <p>3 tremolite breaking to give compact particles," correct?</p> <p>4 A. It also said, "Those fibres formed were</p> <p>5 short and had a very large diameter." So fibers were</p> <p>6 formed. But, yeah, you're correct.</p> <p>7 Q. So, again, it's his opinion that there</p> <p>8 was no asbestos in that test, correct?</p> <p>9 MS. O'DELL: Object to the form.</p> <p>10 MS. SCOTT: Objection.</p> <p>11 BY MR. FROST:</p> <p>12 Q. But that the tremolite was not</p> <p>13 asbestiform. I think they were just called the</p> <p>14 amphibole, but the amphibole that he found was not</p> <p>15 asbestos, correct?</p> <p>16 A. Correct.</p> <p>17 Q. Turning back to your report, page 10, the</p> <p>18 "Mines in Vermont." So I think we talked about it a</p> <p>19 little bit, but I think you and I will agree the</p> <p>20 Appalachian ultramafic belt is where the talc is found</p> <p>21 in Vermont, correct? I think it's your second sentence.</p> <p>22 A. Yes. Yeah.</p> <p>23 Q. Now, do you have the opinion that all the</p> <p>24 ultramafic rocks within the Appalachian belt had the</p> <p>25 same general metamorphic histories and formation</p>
<p style="text-align: right;">Page 171</p> <p>1 reference to --</p> <p>2 A. I just recognized it.</p> <p>3 Q. Okay.</p> <p>4 MS. O'DELL: Object to the form.</p> <p>5 BY MR. FROST:</p> <p>6 Q. So if you look at the fourth paragraph</p> <p>7 down on page 121, Pooley's page 121, it's page 210 of</p> <p>8 the Bates number. The conclusion is "The only</p> <p>9 asbestos-type mineral to be detected in the hand samples</p> <p>10 was tremolite, which was found in three specimens." If</p> <p>11 you go down to the next sentence, it says, "no tremolite</p> <p>12 was detected in the talc-type specimens." Is that</p> <p>13 right?</p> <p>14 MS. O'DELL: Object to the form.</p> <p>15 A. That's what it says, yes.</p> <p>16 BY MR. FROST:</p> <p>17 Q. Okay. So, again, Pooley did not find any</p> <p>18 tremolite in the actual ore or the talc, correct?</p> <p>19 MS. O'DELL: Object to the form.</p> <p>20 MS. SCOTT: Objection.</p> <p>21 A. As it reads, yes.</p> <p>22 BY MR. FROST:</p> <p>23 Q. And if you go to the next page, page 122,</p> <p>24 it's the first full paragraph, the second paragraph on</p> <p>25 the page. About halfway down, it reads, "Particles</p>	<p style="text-align: right;">Page 173</p> <p>1 histories and profiles?</p> <p>2 A. No. There would be some variability.</p> <p>3 Q. Okay. I agree with you. So have you</p> <p>4 ever looked at the local geology for the formation</p> <p>5 associated with the Hammondsville mine?</p> <p>6 A. I've never been on site. I've never been</p> <p>7 to the mine.</p> <p>8 Q. Have you ever looked at any geological</p> <p>9 survey specific to the Hammondsville mine deposit?</p> <p>10 A. The Hammondsville?</p> <p>11 Q. Yes.</p> <p>12 A. Yeah. Yeah. I see its geological</p> <p>13 survey.</p> <p>14 Q. I see the one you've typed here. That's</p> <p>15 really just geological survey showing you where it is,</p> <p>16 correct? That doesn't tell you about the morphology and</p> <p>17 the geological deposit formation?</p> <p>18 A. I think there's some geologic data that's</p> <p>19 associated with it. I don't remember specifics.</p> <p>20 Q. Okay. So and this is true for -- it's</p> <p>21 27, 28, 29 and 30, your footnotes, correct? These are</p> <p>22 all, you know, USGS website hits for Hamm, et cetera?</p> <p>23 A. Yeah.</p> <p>24 Q. Have you ever looked at any of the USGS</p> <p>25 actual reports or surveys that were done examining the</p>

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<p style="text-align: right;">Page 174</p> <p>1 talc in these particular mines?</p> <p>2 A. I believe I have.</p> <p>3 Q. Do you recall which ones they are?</p> <p>4 A. Not specifically at the moment.</p> <p>5 MS. SCOTT: Before you get into this</p> <p>6 next --</p> <p>7 MR. FROST: Do you want to take a break?</p> <p>8 MS. SCOTT: Yeah, let's do that. We've</p> <p>9 been going about an hour and a half, I think, is</p> <p>10 that right, or about an hour?</p> <p>11 MS. O'DELL: Hour and 13 minutes.</p> <p>12 VIDEOGRAPHER: We're now going off the</p> <p>13 record. The time is 2:39.</p> <p>14 (A recess was taken from 2:39 to 2:58)</p> <p>15 VIDEOGRAPHER: We're now back on record,</p> <p>16 and the time is 2:58.</p> <p>17 (Exhibit 15 was marked for</p> <p>18 identification.)</p> <p>19 BY MR. FROST:</p> <p>20 Q. All right. I'm going to start -- can you</p> <p>21 grab, I think, number 15? It's the 1951 geological</p> <p>22 survey from Chidester. Have you ever seen this article</p> <p>23 before?</p> <p>24 A. I don't remember. Let me look at my</p> <p>25 references, the author or the agency. It doesn't appear</p>	<p style="text-align: right;">Page 176</p> <p>1 geological survey?</p> <p>2 A. As stated, yeah.</p> <p>3 Q. Any reason this would not have come up in</p> <p>4 your search?</p> <p>5 MS. SCOTT: Objection.</p> <p>6 A. I didn't search for this particular</p> <p>7 document. When I was doing my search for the</p> <p>8 peer-review literature, you know, I use, like, Web of</p> <p>9 Science. So Web of Science has, essentially, this</p> <p>10 higher level of peer-review material. So this isn't</p> <p>11 necessarily -- these types of reports aren't included in</p> <p>12 that, but I did use Google to search things, and that's</p> <p>13 how I found some of the other things. So -- but, no, I</p> <p>14 don't believe that I've seen this report.</p> <p>15 BY MR. FROST:</p> <p>16 Q. Okay. Given your rendering opinions</p> <p>17 about the geology specifically at the Vermont talc</p> <p>18 deposits, any particular reason you didn't search the</p> <p>19 geological surveys, the USGS surveys regarding the</p> <p>20 areas?</p> <p>21 MS. SCOTT: Objection.</p> <p>22 A. I looked at the literature that I thought</p> <p>23 was relevant, based on my professional opinion.</p> <p>24 BY MR. FROST:</p> <p>25 Q. The next one marked. Take a look at --</p>
<p style="text-align: right;">Page 175</p> <p>1 to be on my reference list.</p> <p>2 Q. Okay. Turn to page 28 of the report.</p> <p>3 MS. SCOTT: And, Doctor, feel free to</p> <p>4 take a look at the entirety of the report if you</p> <p>5 need to.</p> <p>6 A. Okay. I'm not sure.</p> <p>7 MS. SCOTT: Do you have one?</p> <p>8 MR. FROST: Do you need a copy?</p> <p>9 MS. SCOTT: Yes.</p> <p>10 MR. FROST: I apologize.</p> <p>11 MS. SCOTT: That's okay. Thanks.</p> <p>12 MR. FROST: You're welcome. Sorry about</p> <p>13 that.</p> <p>14 MS. SCOTT: No problem.</p> <p>15 BY MR. FROST:</p> <p>16 Q. And my question about this paper is: You</p> <p>17 agree with me, turning to page 28, that this geological</p> <p>18 survey specifically talks about the Hammondsville talc</p> <p>19 mine, correct?</p> <p>20 A. Turn to page 28. Let's see here.</p> <p>21 Q. About halfway down the first column,</p> <p>22 "Hammondsville talc quarry, Locality 117."</p> <p>23 A. 28, Locality 117. Okay. I see that.</p> <p>24 Q. So you agree with me this paper talks</p> <p>25 about the Hammondsville talc mine, correct, this</p>	<p style="text-align: right;">Page 177</p> <p>1 yep, the next one.</p> <p>2 MS. O'DELL: What's the exhibit number on</p> <p>3 this one?</p> <p>4 MR. FROST: Sixteen.</p> <p>5 (Exhibit 16 was marked for</p> <p>6 identification.)</p> <p>7 BY MR. FROST:</p> <p>8 Q. And, again, this is Chidester 1964.</p> <p>9 A. It's the geological survey. Let me check</p> <p>10 and see if I have that. It doesn't look like I have</p> <p>11 that in the reference list.</p> <p>12 Q. Turn to pages --</p> <p>13 A. So let me look. Can I look at the report</p> <p>14 and --</p> <p>15 Q. Yes.</p> <p>16 A. -- just see what the nature is?</p> <p>17 Q. Sure. And, specifically, I'm going to</p> <p>18 turn your attention to 48 and 49.</p> <p>19 A. 48 and 49, okay. Let me look at the</p> <p>20 report in general here.</p> <p>21 Q. The question, then, is going to be: You</p> <p>22 agree with me that in this USGS survey, they</p> <p>23 specifically ran chemical analysis of ore coming out of</p> <p>24 the Hammondsville mine? I guess it's typed ore mill</p> <p>25 product.</p>

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<p>1 A. Yes. It says, "Chemical analyses of a 2 variety of talc in Vermont," and the year on this is -- 3 well, I'm sorry. 4 Q. I believe it's 19 -- 5 A. So 40a, 40b and 40c. The source is from 6 Spence, so let's see what Spence 1940 is. So at that 7 period of time, most things were done by wet chemistry, 8 and so the -- there were limitations as far as the 9 detection limits. So I'm sorry. 1940. 10 Q. Well, again, my question -- 11 A. Yeah. Go ahead with your question. 12 Q. Despite the fact that there is specific 13 testing of ore in this document as well as Spence, 14 neither of those two documents ever came up in your 15 searches, correct? 16 MS. SCOTT: Objection. 17 BY MR. FROST: 18 Q. And this is testing specific to the ore 19 from the Hammondsville mine. Do you agree with me that 20 neither Spence nor this paper came up in your searches? 21 A. Correct. I mean, you know, so one of the 22 things is that it depends -- 23 Q. Well, answer my question. 24 A. Yep. I'm seeing if it -- it's not -- 25 actually, Spence is not cited in this document.</p>	<p>1 MS. O'DELL: Let him finish. 2 A. Power diffraction was beginning to be 3 common and then chemical analyses. So I didn't 4 necessarily exclude it based on -- or I didn't really -- 5 I just -- I didn't find it, but I didn't -- you know, 6 these are older references and I would not -- 7 BY MR. FROST: 8 Q. That was question is you didn't find 9 this, right? 10 MS. SCOTT: Objection. 11 A. I did not search for a lot of the older 12 literature because the analytical methods dated, 13 predated what appear to be the operational -- operation 14 timelines or -- 15 BY MR. FROST: 16 Q. But it doesn't sound like you searched 17 for any USGS surveys regarding these specific mines; is 18 that fair? That wouldn't have come up in your search? 19 MS. SCOTT: Objection. 20 A. So specific mines may not -- they're not 21 necessarily in USGS reports. Mines tend to show up in 22 USGS reports if there's permission or -- 23 BY MR. FROST: 24 Q. Sir, I have a limited amount of time, and 25 I really need you to just answer my questions. So my</p>
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<p>1 Q. It appears to be. Spence? 2 A. Pearre, Pearre, Pearre, Pearre, Perry, 3 Pratt, Quinn. 4 Q. If you at page 61, Spence, HS 1940. 5 A. It's not listed in the -- 6 Q. Page 61, selected bibliography? 7 A. 61. I'm sorry. I don't see it. Oh, 8 Spence. I was thinking Pence. Okay. Right. Very 9 good. 10 Q. Okay. 11 A. So, essentially, the -- I don't think the 12 company was mining Hammondsville at that time, was it? 13 Q. My question becomes, did these come up -- 14 despite the fact that there's testing specifically of 15 ore from Hammondsville in both Spence and this, this 16 report did not come up or the Spence report come up in 17 your searches; is that correct? 18 MS. SCOTT: Objection. 19 A. Correct, because the analytical 20 techniques at the time, certainly for electron 21 microscopy, was in its infancy. Power diffraction 22 was -- 23 BY MR. FROST: 24 Q. So you're saying it didn't come up in 25 your computer search because of --</p>	<p>1 question is -- 2 A. I'm trying to give a thorough answer. 3 Q. No, no. The question is -- it's a very 4 simple question. Did you search USGS reports for the 5 specific mines that Johnson & Johnson used in Vermont? 6 MS. SCOTT: Objection. 7 A. I don't remember. 8 BY MR. FROST: 9 Q. Okay. And you certainly didn't cite 10 them. 11 A. I did not cite these. I did not cite 12 these. 13 Q. Do you know what NIOSH is? 14 A. Yes. 15 Q. Okay. Are you aware that NIOSH has 16 funded an epidemiological study based out of the workers 17 of the Vermont mines? 18 MS. SCOTT: Objection. 19 A. I'm not a medical expert. I only know 20 NIOSH really exists. I use it for the basic definition. 21 BY MR. FROST: 22 Q. So is that a no? 23 A. I'm sorry. Repeat the question, please. 24 Q. I said, are you aware that NIOSH has run 25 an epidemiological study of the workers at the Vermont</p>

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<p>1 mines?</p> <p>2 A. No I am not. I don't remember.</p> <p>3 MR. FROST: We'll mark this as -- I</p> <p>4 believe this is new 17.</p> <p>5 (Exhibit 17 was marked for</p> <p>6 identification.)</p> <p>7 BY MR. FROST:</p> <p>8 Q. Have you ever seen this paper? Do you</p> <p>9 know who Dr. Boundy is?</p> <p>10 A. So what is the journal? I don't have it</p> <p>11 cited as Boundy. The journal -- is this a National</p> <p>12 Institutes of Health paper, just so I can be sure?</p> <p>13 Q. I believe it is a journal called Dust and</p> <p>14 Disease.</p> <p>15 A. Oh, I don't think I cited anything from</p> <p>16 Dust and Disease.</p> <p>17 Q. Okay.</p> <p>18 A. So in occupational exposures,</p> <p>19 non-asbestiform talc in Vermont. Okay?</p> <p>20 Q. Is this not something that came up in</p> <p>21 your search?</p> <p>22 MS. SCOTT: Objection.</p> <p>23 A. No. I'm not -- I'm sorry. Dust and</p> <p>24 Disease?</p> <p>25</p>	<p>1 explanations about other parts of the report that don't</p> <p>2 have to do with question are just taking up my time on</p> <p>3 the record. So I'm not trying to be rude, but I'm</p> <p>4 running out of time, so I'm trying to move it along.</p> <p>5 MS. SCOTT: But to be fair, you're also</p> <p>6 asking him about an epidemiological study. He's</p> <p>7 not an epidemiologist.</p> <p>8 BY MR. FROST:</p> <p>9 Q. And my question was whether or not this</p> <p>10 was something he would have searched for, and the answer</p> <p>11 is no, right?</p> <p>12 A. No. I would not go to a journal called</p> <p>13 Dust and Disease. Are you okay on time?</p> <p>14 Q. You don't need to worry about that.</p> <p>15 That's a lawyer thing.</p> <p>16 MS. O'DELL: Yes.</p> <p>17 BY MR. FROST:</p> <p>18 Q. Turning back to your report, looking at</p> <p>19 the bottom of page 10, we then move on to the mines in</p> <p>20 China.</p> <p>21 A. I requested documents on -- I requested</p> <p>22 documents on China, mines in China. There were --</p> <p>23 apparently, there was not a whole lot of information. I</p> <p>24 know Dr. Longo tested materials from China, but I don't</p> <p>25 think -- I mean, I made a request for cores. I made</p>
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<p>1 BY MR. FROST:</p> <p>2 Q. That's correct.</p> <p>3 A. Yeah. I'm not a medical --</p> <p>4 Q. So you wouldn't have --</p> <p>5 A. -- expert.</p> <p>6 Q. Sorry.</p> <p>7 A. So I'm not a medical expert, so I didn't.</p> <p>8 Q. So you wouldn't have looked at any</p> <p>9 journals outside of your specific field, because I will</p> <p>10 relate to you that they tested talc from the various</p> <p>11 mines and found that there was no asbestos in it based</p> <p>12 on the NIOSH study. It's not something you relied on?</p> <p>13 A. So there's --</p> <p>14 MS. O'DELL: Object to the form. Excuse</p> <p>15 me, Doctor. Object to the form. You may</p> <p>16 answer.</p> <p>17 A. In all these questions are still -- I did</p> <p>18 not look at this paper, but this paper does not negate</p> <p>19 the findings of the rest of the report. I've tried to</p> <p>20 take a broad net.</p> <p>21 BY MR. FROST:</p> <p>22 Q. Sir, again --</p> <p>23 A. I have a broad net.</p> <p>24 Q. I'm asking very simply yes or no</p> <p>25 questions about whether he searched for things,</p>	<p>1 requests for testing results, including TEM, XRD, bulk</p> <p>2 chemistry. But the data that I was able to have was, as</p> <p>3 far as I did actually, I tried to search on Web of</p> <p>4 Science and other things about talc deposits in China,</p> <p>5 and I could not discernibly find anything. I think</p> <p>6 there's Chinese references, but I don't speak Chinese</p> <p>7 and --</p> <p>8 Q. Sure.</p> <p>9 A. -- I couldn't really translate those.</p> <p>10 Q. And by saying you asked, you asked</p> <p>11 plaintiffs' counsel, and they provided you what they</p> <p>12 provided you, correct?</p> <p>13 MS. SCOTT: Objection.</p> <p>14 A. Yeah. So I want to use company</p> <p>15 documents, so give the company, essentially, as I</p> <p>16 believe I was supposed to do, so the company documents</p> <p>17 are -- I mean.</p> <p>18 BY MR. FROST:</p> <p>19 Q. Okay. And like we established before,</p> <p>20 you have no way of knowing if there are any other</p> <p>21 documents that just weren't given to you by plaintiffs'</p> <p>22 counsel, right?</p> <p>23 MS. SCOTT: Objection.</p> <p>24 A. Well, I did. I did search -- I did</p> <p>25 search the Internet to try to find --</p>

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<p>1 BY MR. FROST: 2 Q. I'm talking about documents. 3 A. The documents? 4 Q. Yes. You have no way of knowing if what 5 plaintiffs gave you is the complete set of documents 6 that relate to the mine, right? 7 A. I expected -- 8 MS. SCOTT: Objection. 9 A. Yeah. Of all the documents that exist, I 10 expect that it's not each and every single document. 11 BY MR. FROST: 12 Q. So you've made your review and your 13 opinions on the China based on what is admittedly an 14 incomplete set of documents provided to you by 15 plaintiffs' counsel, right? 16 MS. SCOTT: Object to the form. 17 A. I don't know if it's fully -- I made 18 requests for the China for as much -- all the 19 information on China that there was and, to my 20 knowledge, what was provided, and then what I looked at, 21 I tried to search things on my own. There just is 22 apparently not a lot I would consider. I would 23 certainly consider reviewing documents on China. I 24 would certainly consider translated documents, so 25 someone who's got an expertise but --</p>	<p>1 metal contents like lead, cobalt, chromium, iron, nickel 2 and titanium, correct? 3 A. Correct. 4 Q. And then you cite to JNJ 59273, right? 5 A. Right. 6 Q. Okay. Let's look at that document. 7 A. It's got 750 parts per million of 8 titanium in it. It's actually low. It's like .2. 9 (Exhibit 18 was marked for 10 identification.) 11 BY MR. FROST: 12 Q. I'll divert your attention to page 2086. 13 I take it the comment at the bottom of 2086 is where 14 you're getting this information from, right? 15 MS. SCOTT: Objection. 16 A. I looked at the data. Actually, I'm 17 looking for the data table that I saw the other day. 18 Yeah, so 2078, titanium 750. The lead there is 12.7 on 19 the previous table. Let's look and see what the 20 concentrations are. 21 BY MR. FROST: 22 Q. You're on 2078? 23 A. I am on 2078. 24 Q. Okay. 25 A. And so --</p>
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<p>1 BY MR. FROST: 2 Q. Again, I'm trying to rein in your answers 3 here -- 4 A. Okay. 5 Q. -- to what we're talking about. But I 6 want to be clear. The requests you made weren't to 7 either Imerys or Johnson & Johnson. You made those 8 requests to plaintiffs' counsel? 9 A. Yes. 10 Q. And then plaintiffs' counsel provided 11 back to you a set of documents? 12 A. Yes. 13 Q. And you can't tell me whether or not that 14 set consists of all documents that you requested related 15 to the Chinese mines, right? 16 MS. SCOTT: Objection. 17 A. I cannot without certainty. 18 BY MR. FROST: 19 Q. All right. So let's look at what you 20 opine. Page 11, the second paragraph, you state, as far 21 back as 1983, and again, we know in 1983, Johnson & 22 Johnson was not sourcing talc from China, right? 23 A. Correct. 24 Q. Defendants had information indicating 25 that Chinese talc contains higher than normal heavy</p>	<p>1 Q. Do you see the top of 2078 that that 2 chart relates to something called "Kwangsi No. 1 talc"? 3 A. Yes. 4 Q. Do you believe that Kwangsi No. 1 talc 5 was the talc ever used by Johnson & Johnson? 6 A. It's unclear. I don't. 7 Q. Well, in your report, I think you note 8 that they use Kwangsi No. 1 and Kwangsi No. 2, correct? 9 A. Correct. 10 MS. O'DELL: Objection. 11 A. I think -- again, I'm not an expert in 12 Chinese language. 13 BY MR. FROST: 14 Q. But you'd agree with me that Kwangsi No. 15 1 is not Kwangsi talc, correct? It's a different ore? 16 A. I don't really know. Names of mines 17 change and things, but, potentially, they seem 18 different. That's reasonable. But in my sentence, I 19 say defense information indicating that Chinese talc 20 contains higher than normal levels and, you know, the 21 metals are there. So I think that statement is 22 consistent with the chart on page 2078 and 2086, and 23 let's look at -- it's been a while since I looked at the 24 document. 25 Q. Hold on. Let me walk you through it.</p>

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<p>1 A. I'd like to review --</p> <p>2 Q. Well, I want to talk about your</p> <p>3 statement, then. When you're saying Chinese talc is</p> <p>4 higher than normal --</p> <p>5 A. Can I?</p> <p>6 Q. No.</p> <p>7 MS. SCOTT: Let him ask the question.</p> <p>8 BY MR. FROST:</p> <p>9 Q. Can you answer my question, please?</p> <p>10 A. Okay. Good.</p> <p>11 Q. When you say Chinese talc contains higher</p> <p>12 than normal heavy metal contents, you're talking about</p> <p>13 all talc from China, not necessarily the Chinese talc</p> <p>14 that Johnson & Johnson was using? Is that what you're</p> <p>15 telling me?</p> <p>16 MS. SCOTT: Objection.</p> <p>17 A. I'm sorry.</p> <p>18 BY MR. FROST:</p> <p>19 Q. I'll ask you the question again, so you</p> <p>20 don't have to read it.</p> <p>21 A. Yeah.</p> <p>22 Q. So in your report, when you're talking</p> <p>23 about Chinese talc, you're talking about talc from the</p> <p>24 country of China, not the Chinese talc ore that Johnson</p> <p>25 & Johnson was using? Is that what you're telling us?</p>	<p>1 refer to this as an indication that there are</p> <p>2 problematic materials in Chinese ore. Obviously, it was</p> <p>3 investigated for a reason, so they were interested in it</p> <p>4 at some level.</p> <p>5 BY MR. FROST:</p> <p>6 Q. Okay. But you agree with me you have no</p> <p>7 way to tell us one way or the other that any of the</p> <p>8 tests of any of the ore in this document actually relate</p> <p>9 to the talcum powder that 20 years, 30 years later made</p> <p>10 it into Johnson & Johnson talcum powder products?</p> <p>11 MS. O'DELL: Objection.</p> <p>12 A. The -- the documentation provided to me</p> <p>13 is -- there's many gaps.</p> <p>14 BY MR. FROST:</p> <p>15 Q. Sir, I'm talking about this document.</p> <p>16 Focus on this document. So my question is: This</p> <p>17 document, is there anywhere in this document that says</p> <p>18 the talc that Johnson & Johnson uses 20 years later for</p> <p>19 talcum powder has constituents? I understand we're</p> <p>20 talking --</p> <p>21 A. Has constituents?</p> <p>22 Q. Has the constituents we're talking about</p> <p>23 here. You know, that "Defendant had information</p> <p>24 indicating that Chinese talc contains higher than normal</p> <p>25 heavy metal contents like lead, cobalt, chromium, nickel</p>
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<p>1 MS. SCOTT: Objection.</p> <p>2 A. I meant, essentially, both more Chinese,</p> <p>3 Chinese talc, meaning talc within the boundaries of</p> <p>4 China has more or has contaminants and would be of</p> <p>5 potential concern.</p> <p>6 BY MR. FROST:</p> <p>7 Q. That's a general statement as to all</p> <p>8 talcs coming out of all talc regions of China?</p> <p>9 MS. O'DELL: Object to the form.</p> <p>10 BY MR. FROST:</p> <p>11 A. Well, it's specific to this example, and</p> <p>12 as an example, I think there's, there's a lot of concern</p> <p>13 in the general environmental literature about materials</p> <p>14 in China in general so --</p> <p>15 Q. And by concerns over materials in</p> <p>16 general, you're talking about now everything coming out</p> <p>17 of China as a generalization?</p> <p>18 MS. SCOTT: Objection.</p> <p>19 A. Not everything.</p> <p>20 BY MR. FROST:</p> <p>21 Q. But you're talking about, like, the lead</p> <p>22 concerns out of manufactured products like toys, and</p> <p>23 we're including this now in your statement, right?</p> <p>24 MS. SCOTT: Objection.</p> <p>25 A. No. I'm sorry. Let me just be clear. I</p>	<p>1 and titanium." Is there anything in here --</p> <p>2 A. They simply knew that this is how I --</p> <p>3 they simply know that this report existed, right?</p> <p>4 Q. You have to listen to my question. You</p> <p>5 can't tell me one way or the other that this report in</p> <p>6 any way relates to any talc ever used by Johnson &</p> <p>7 Johnson for its talcum powder, right?</p> <p>8 MS. SCOTT: Objection.</p> <p>9 A. I do not have a chain of custody, so,</p> <p>10 yes.</p> <p>11 Q. Okay.</p> <p>12 A. But the way the sentence is phrased, the</p> <p>13 sentence is general.</p> <p>14 Q. Yes. We've established that now.</p> <p>15 MS. O'DELL: Excuse me.</p> <p>16 BY MR. FROST:</p> <p>17 Q. No, no. I'm saying --</p> <p>18 MS. O'DELL: You interrupted him -- let</p> <p>19 him finish.</p> <p>20 MR. FROST: Sure.</p> <p>21 BY MR. FROST:</p> <p>22 Q. In general --</p> <p>23 MS. O'DELL: Stop talking. Let him talk.</p> <p>24 Thank you.</p> <p>25 A. So the sentence is general. Defendants</p>

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<p>1 have information indicating that Chinese talc contains</p> <p>2 higher than normal levels of lead, cobalt, chromium. So</p> <p>3 I feel that this document supports that statement. It</p> <p>4 doesn't say all talc, but they had knowledge that</p> <p>5 some --</p> <p>6 BY MR. FROST:</p> <p>7 Q. Some talc?</p> <p>8 A. -- talc had issues.</p> <p>9 Q. Okay.</p> <p>10 THE WITNESS: My thing is -- I think it</p> <p>11 stopped. What time? It says 1520.</p> <p>12 MS. SCOTT: Did you hit "follow"?</p> <p>13 THE WITNESS: Yeah, I have hit "follow"</p> <p>14 several times.</p> <p>15 BY MR. FROST:</p> <p>16 Q. All right. While they're sorting that</p> <p>17 out, I'll continue to ask my questions.</p> <p>18 A. Okay.</p> <p>19 Q. All right. Page 11 of your report,</p> <p>20 second full paragraph starts, "In the Guangxi Province."</p> <p>21 A. Yes.</p> <p>22 Q. If you look down the citation, you say,</p> <p>23 after it, it says, "In 'Talc Geology, Resources,</p> <p>24 Production and Market Study, Guangxi Autonomous Region,'</p> <p>25 asbestos was discovered in fractures of the talc ore</p>	<p>1 deposits are geologically related, to the best of my</p> <p>2 ability. Again, there is some paucity of data, but it</p> <p>3 seemed, from what I could gather, that these are</p> <p>4 geologically related.</p> <p>5 BY MR. FROST:</p> <p>6 Q. So sitting here today, you can tell me</p> <p>7 that you've specifically looked at the Maanshan deposit</p> <p>8 and the -- I apologize to the court reporter for these</p> <p>9 names -- and Zhizhua Mine, and you're confident and you</p> <p>10 can tell me that you have seen sources that shows those</p> <p>11 two exact deposits are similar and come from the same</p> <p>12 areas? And if that's true, what's your source?</p> <p>13 A. Let me -- so...</p> <p>14 MS. O'DELL: Objection.</p> <p>15 A. So asbestos was discovered and fractures</p> <p>16 of the talc ore body of the Maanshan deposit looking in</p> <p>17 the Shanglin region. And the question is am I certain</p> <p>18 that talc --</p> <p>19 BY MR. FROST:</p> <p>20 Q. You just told me that you've seen</p> <p>21 something that says Maanshan is the same geological</p> <p>22 formation?</p> <p>23 A. Can we look at 413792?</p> <p>24 Q. I don't have it. Is that the one we just</p> <p>25 looked at, though?</p>
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<p>1 body of the Maanshan talc deposit located in the</p> <p>2 Shanglin region."</p> <p>3 Did I read that right, or close enough,</p> <p>4 anyway, on the pronunciations?</p> <p>5 A. Yes.</p> <p>6 Q. Did Johnson & Johnson ever use talc from</p> <p>7 the Maanshan deposit?</p> <p>8 A. I'm not sure. I'm confused by that, the</p> <p>9 Chinese words, so I'm not sure. But, again, there</p> <p>10 was -- so I don't know for sure, but there was a paucity</p> <p>11 of data relating to Chinese, I think.</p> <p>12 Q. You specifically state, if you look back</p> <p>13 at page 8 --</p> <p>14 A. I forget.</p> <p>15 Q. -- of your report, you state, "2002 to</p> <p>16 present: Zhizhua Mine, Guigang Province, China.</p> <p>17 Product Name: Guangxi No. 2 and Guangxi No. 2A"</p> <p>18 A. Yeah. Those are two.</p> <p>19 Q. Maanshan is not the Guangxi mine that's</p> <p>20 mentioned there, correct?</p> <p>21 A. Correct.</p> <p>22 Q. And you have no evidence that Johnson &</p> <p>23 Johnson ever sourced talc from the Maanshan deposit?</p> <p>24 MS. SCOTT: Objection.</p> <p>25 A. Correct. But as I understand it, the</p>	<p>1 MS. SCOTT: No.</p> <p>2 MR. FROST: A different one. I don't</p> <p>3 have it, so, no. I mean, you guys can do it</p> <p>4 during your time.</p> <p>5 MS. O'DELL: If he wants to see the</p> <p>6 document and it's available to him --</p> <p>7 All right. If he has it.</p> <p>8 A. Can we? So it's Imerys 413792, Imerys.</p> <p>9 VIDEOGRAPHER: Watch your mic. Doctor,</p> <p>10 watch your mic.</p> <p>11 A. That's 413792. 413792. It is a JNJ.</p> <p>12 BY MR. FROST:</p> <p>13 Q. No. It is an Imerys.</p> <p>14 VIDEOGRAPHER: Do you want to go off the</p> <p>15 record?</p> <p>16 MR. FROST: Let's go off the record,</p> <p>17 please.</p> <p>18 VIDEOGRAPHER: We're now going off</p> <p>19 record. The time is 3:32.</p> <p>20 (Recess taken from 3:32 to 3:39.)</p> <p>21 VIDEOGRAPHER: We're now back on record.</p> <p>22 The time is 3:39.</p> <p>23 BY MR. FROST:</p> <p>24 Q. Okay. So do you believe this document</p> <p>25 supports that the geology of Zhizhua and Maanshan are</p>

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<p>1 the same?</p> <p>2 A. So Guangxi is an autonomous region.</p> <p>3 Q. Okay.</p> <p>4 A. And there are different mines within that</p> <p>5 autonomous region.</p> <p>6 Q. So, again, do you have anything that</p> <p>7 shows me that the formation at the Zhizhua Mine are the</p> <p>8 same as the Maanshan mine?</p> <p>9 A. No. I don't think so, or I'm unclear.</p> <p>10 I'm confused by the names.</p> <p>11 Q. All right. That's fine. Moving on on</p> <p>12 page 11, the paragraph that starts about halfway down</p> <p>13 the page, "Beginning in July of 2004."</p> <p>14 A. Uh-huh.</p> <p>15 Q. And then the next two paragraphs sort of</p> <p>16 preceding that, do you agree with me that these all</p> <p>17 relate to a mine visit in the Liboshikuang Mine of the</p> <p>18 Shandong Province?</p> <p>19 A. I'm confused by the names. I would need</p> <p>20 to look at the document.</p> <p>21 Q. Yeah. And Hubei and Shandong. Well,</p> <p>22 here. We'll start with the first paragraph. "Beginning</p> <p>23 in ... 2004, Rio Tinto began investigating talc</p> <p>24 operations and talc potential in the provinces of Hubei</p> <p>25 and Shandong." Did I read that correctly?</p>	<p>1 anything to refute that statement?</p> <p>2 MS. SCOTT: Objection.</p> <p>3 A. I have nothing to refute or endorse. I</p> <p>4 do know the geology of China is very chopped up. It's</p> <p>5 extremely complex. So you can have areas that are</p> <p>6 geologically connected that are distant from each other.</p> <p>7 So Tianchen is a basin area in north central China. I</p> <p>8 have colleagues that work there, and essentially, there</p> <p>9 are major displacements that occur.</p> <p>10 So, again, I didn't have details of</p> <p>11 China, but, essentially, China is very complex, and you</p> <p>12 can have parts of the geology disperse. Yes, I was not</p> <p>13 aware that they were separated by geographic distance.</p> <p>14 That doesn't preclude that.</p> <p>15 BY MR. FROST:</p> <p>16 Q. Well, I was going to say without</p> <p>17 speculating, your can't tell me whether or not the talc</p> <p>18 districts of Hubei and Shandong are the same as the talc</p> <p>19 district in Guangxi, for example, correct?</p> <p>20 MS. SCOTT: Objection.</p> <p>21 BY MR. FROST:</p> <p>22 Q. Sitting here today --</p> <p>23 A. Correct. But the statement as "Rio Tinto</p> <p>24 began investigating talc operations and talc potential</p> <p>25 in the provinces of Hubei and Shandong."</p>
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<p>1 A. Yeah. So, to my knowledge, that</p> <p>2 paragraph is correct.</p> <p>3 Q. But I didn't ask if it was correct.</p> <p>4 A. Okay.</p> <p>5 Q. My question is: Do you agree with me</p> <p>6 that Hubei and Shandong are different areas of China</p> <p>7 than Guangxi?</p> <p>8 MS. SCOTT: Objection.</p> <p>9 A. I don't know.</p> <p>10 BY MR. FROST:</p> <p>11 Q. Okay. Did you ever look up Hubei and</p> <p>12 Shandong and compare them to where Guangxi sits?</p> <p>13 A. I don't remember. If I did, I -- you</p> <p>14 know, I got -- the nomenclature, the names were</p> <p>15 confusing. So I did -- I try to look at Google Earth</p> <p>16 and figure things out. But, again, I don't think there</p> <p>17 was, like, a location map that was provided. The data</p> <p>18 from China was very limited. There's no -- I don't</p> <p>19 think there's any GPS coordinates, which is another</p> <p>20 thing that's kind of odd. Okay. Go ahead.</p> <p>21 Q. If I were to represent to you that</p> <p>22 they're about 2,000 kilometers away from each other, the</p> <p>23 Hubei and Shandong are coastal by Shanghai and Guangxi</p> <p>24 is southern and internal and they're about</p> <p>25 2,000 kilometers away from each other, would you have</p>	<p>1 Q. Yes. Just answer my questions, okay?</p> <p>2 And, again, there's no evidence that talc ever came from</p> <p>3 Hubei and Shandong that was used in Johnson & Johnson</p> <p>4 talcum powder. You, sitting here today, without</p> <p>5 speculating, can't tell me that Johnson & Johnson ever</p> <p>6 used talc that came from Hubei and Shandong, correct?</p> <p>7 A. Correct.</p> <p>8 Q. And then it continues on, and it starts</p> <p>9 talking about the detailed visit to the Liboshikuang</p> <p>10 Mine in the Shandong province, correct? It's two</p> <p>11 paragraphs down. It talks about the field report and</p> <p>12 "the report detailed a visit?</p> <p>13 A. The second paragraph on the bottom?</p> <p>14 Q. Yes.</p> <p>15 A. In Shandong? Okay.</p> <p>16 Q. Okay. And, again, it talks about a mine</p> <p>17 that you have no evidence whatsoever whether or not this</p> <p>18 has any geological similarity to the Shandong province</p> <p>19 or the Guangxi province, correct?</p> <p>20 MS. SCOTT: Objection.</p> <p>21 A. Specifically, no. There is no data that</p> <p>22 was --</p> <p>23 BY MR. FROST:</p> <p>24 Q. So what I'm getting at here is I'm a</p> <p>25 little confused why we're talking about talc districts</p>

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<p>1 upon which you have no data that are thousands of</p> <p>2 kilometers away from the mine actually being used by</p> <p>3 Johnson & Johnson.</p> <p>4 MS. SCOTT: Form.</p> <p>5 A. Because just like in, as you pointed out</p> <p>6 for the Appalachians, we have this very large district</p> <p>7 that extends hundreds of kilometers. Based on the</p> <p>8 limited data that was available to me, it's likely that,</p> <p>9 essentially, talc deposits are genetically related in</p> <p>10 some way.</p> <p>11 BY MR. FROST:</p> <p>12 Q. Except that didn't you just tell me</p> <p>13 without speculating --</p> <p>14 MS. O'DELL: Excuse me.</p> <p>15 MR. FROST: Old on.</p> <p>16 MS. O'DELL: He was not finished.</p> <p>17 A. So, basically, it's reasonable, you know,</p> <p>18 so if you have -- you know, you have a deposit of</p> <p>19 something, and you have similar deposits of that same</p> <p>20 something, that it's reasonable that you would expect</p> <p>21 there to be some connection or relationship. That's</p> <p>22 something that we do in geology all the time,</p> <p>23 essentially develop hypotheses as far as spatial</p> <p>24 relationships of things.</p> <p>25 So, basically, the fact that there's</p>	<p>1 MS. SCOTT: Objection.</p> <p>2 BY MR. FROST:</p> <p>3 Q. You don't know one way or the other; is</p> <p>4 that correct?</p> <p>5 MS. SCOTT: Objection.</p> <p>6 MS. O'DELL: Objection.</p> <p>7 A. With a hundred percent degree of</p> <p>8 certainty, sure. But, geologically, it makes sense that</p> <p>9 things would be related.</p> <p>10 BY MR. FROST:</p> <p>11 Q. Okay. And that's based on what studies</p> <p>12 have you looked at in China that show you can make the</p> <p>13 leap to say that these regions that you don't --</p> <p>14 A. That's --</p> <p>15 Q. Hold on -- that you don't know anything</p> <p>16 about are related?</p> <p>17 MS. SCOTT: Objection.</p> <p>18 A. I base that on, essentially, just the</p> <p>19 nature of tectonics on the planet. Essentially, there's</p> <p>20 no peer review literature.</p> <p>21 BY MR. FROST:</p> <p>22 Q. Turn to page 12. It's the first full</p> <p>23 paragraph. "I have reviewed multiple documents." It is</p> <p>24 the paragraph that starts there. Do you see where I am?</p> <p>25 A. Yes.</p>
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<p>1 60 percent white talc and 40 percent black talc with the</p> <p>2 latter having obvious tremolite association, so that's,</p> <p>3 okay, one thing. And then, notably, it was associated</p> <p>4 with amphibolite-grade metamorphism. Therefore,</p> <p>5 Johnson & Johnson and Imerys had information regarding</p> <p>6 tremolite's presence in the region.</p> <p>7 And if you had indication of the presence</p> <p>8 of something in the region, you know, you might exclude</p> <p>9 that or you would want to do further exploration to sort</p> <p>10 of constrain, as we mentioned earlier, with mining, we</p> <p>11 want to define what's not there and what is there.</p> <p>12 BY MR. FROST:</p> <p>13 Q. But here's where I'm going stop you. All</p> <p>14 of this concerns a region that's thousands of kilometers</p> <p>15 away from the region that's actually being mined, right?</p> <p>16 MS. SCOTT: Objection.</p> <p>17 BY MR. FROST:</p> <p>18 Q. So what does any of this actually have</p> <p>19 anything to do, without speculating, about the talc</p> <p>20 coming from the Zhizhua Mine in the Guangxi Province?</p> <p>21 MS. SCOTT: Objection.</p> <p>22 A. The geology can be potentially related.</p> <p>23 BY MR. FROST:</p> <p>24 Q. See, we're talking about can be here, but</p> <p>25 you're speculating, right?</p>	<p>1 Q. Where is it? The third sentence. You</p> <p>2 know that "The practices and procedures defendants' talc</p> <p>3 fall short of satisfying international standards of</p> <p>4 quality and purity." What international standards of</p> <p>5 quality and purity are you talking about here that you</p> <p>6 didn't cite?</p> <p>7 A. So industrial mineral companies,</p> <p>8 basically, we used the peer-review literature, and</p> <p>9 essentially, things are developed internally to assure</p> <p>10 that you have variability or control, and so it's</p> <p>11 commonly done that you run multiple x-ray diffraction</p> <p>12 analyses on materials, for example. So a company I work</p> <p>13 closely with in Virginia, or have historically, they</p> <p>14 analyze 200 samples a day, essentially, and they do that</p> <p>15 with powder diffraction and, also, XRF.</p> <p>16 There's analytical technologies that</p> <p>17 exist that you can do rapid XRF analyses with a handheld</p> <p>18 device, and that's been around since the early 2000s.</p> <p>19 So, basically, the peer-review literature is one general</p> <p>20 way of doing things.</p> <p>21 Q. And then -- well, hold on. We'll start</p> <p>22 there. What studies? Can you point me a single study</p> <p>23 that talks about the international standards of quality</p> <p>24 and purity that weren't met here?</p> <p>25 MS. SCOTT: Objection.</p>

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<p style="text-align: right;">Page 206</p> <p>1 A. So methods are communicated verbally in 2 industrial mineral companies. So, basically, by 3 interacting with companies, I know, basically, that you 4 analyze things repeatedly, repeatedly trying to 5 constrain the variability. Things aren't necessarily, 6 as far as what individual companies do, they look to the 7 peer-review literature to use or learn what analyses are 8 done and how they are executed. 9 As far as the numbers of things, that's 10 something that's decided by companies, and basically, 11 using general statistical approaches, they want to know 12 what the variation is. So companies that I work with, 13 they commonly will analyze hundreds of, a couple hundred 14 samples a day or a week. 15 Other companies I know, they have 16 dedicated labs that basically analyze hundreds of 17 thousands of samples a week, and it's expected that they 18 maintain that level because, eventually, they can get 19 sold or bought, so they want to be able to prove the 20 reserves and the historical thing. So that's -- that's 21 kind of the international standard is sort of multiple 22 things. It's by experience. 23 Q. Here's what I want to get at. If I want 24 to know what the international standards of quality and 25 purity are, you're telling me there's not any document I</p>	<p style="text-align: right;">Page 208</p> <p>1 you if you want. 2 A. Yeah. I need to look at it, but I think 3 that might be related to gold mining, but Gy is 4 something that's used in general. 5 Q. Is Gy a universally adopted standard for 6 mining practices around the world? 7 A. I think it's commonly used. Again, every 8 company has their own. 9 Q. Why don't we look at Afewu, but, again, 10 you agree with me that Gy is one. There are probably 11 hundreds, if not thousands, of competing theories and 12 methodologies, right? 13 MS. SCOTT: Objection. 14 MS. O'DELL: Objection. 15 A. I don't think that's an accurate 16 statement. 17 BY MR. FROST: 18 Q. But it's certainly not the only one, 19 right? 20 A. Others exist. 21 Q. So you can't tell me that Gy is the 22 universal standard for talc mining, right, and that 23 that's the standard that companies have to follow? 24 That's the, quote, international standard of quality and 25 purity?</p>
<p style="text-align: right;">Page 207</p> <p>1 can go to, any regulation or anything out there. I'm 2 trying to get the basis for your opinion here, and the 3 basis for your opinion here is Dr. Krekeler had told me 4 it's wrong and here's why, and you can't point to any 5 study -- 6 A. So -- 7 MS. O'DELL: Let him finish. 8 THE WITNESS: Okay. 9 BY MR. FROST: 10 Q. -- regulation, mine document, anything 11 out there to support your basis. It's just I, Mark 12 Krekeler, am telling you this. You should believe me. 13 MS. SCOTT: Objection. 14 A. So Gy and the reference. Gy 79 is 15 something that's used sampling of particulate materials 16 there in practice. 17 BY MR. FROST: 18 Q. Let's talk about Gy. Gy is about gold 19 mining, right? 20 A. Gy is about sampling of particulate 21 materials. 22 Q. Related to gold mining, right? 23 A. I don't recall specifically. Was it 24 Afewu? I believe the Afewu. 25 Q. If you look at Afewu, I can mark that for</p>	<p style="text-align: right;">Page 209</p> <p>1 MS. SCOTT: Objection. 2 A. I think it's relevant. 3 BY MR. FROST: 4 Q. We'll mark Afewu. We talked about Afewu. 5 A. So if you're mining -- 6 Q. There's not a question pending, sir. 7 A. Okay. Sorry. 8 MS. O'DELL: This is 20? 9 MR. FROST: 18. 10 COURT REPORTER: 19. 11 MR. FROST: 19? 12 COURT REPORTER: Yes. 13 (Exhibit 19 was marked for 14 identification.) 15 BY MR. FROST: 16 Q. On the first page, it's page 299 on the 17 first column. It's the paragraph that starts, "An 18 essential condition of any sample." 19 A. Okay. I found the paragraph. 20 Q. Okay. About halfway through, it starts 21 talking about the Gy paper. "A number of approaches 22 have been proposed to address these problems. The most 23 notable one is the work of Gy." Do you see where I am? 24 A. Yes. 25 Q. After that, it says, "Most practitioners</p>

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<p>1 have used this model for gold ores, though, without much</p> <p>2 fulfillment in the results." Am I reading that</p> <p>3 correctly?</p> <p>4 A. You're reading what they've said.</p> <p>5 Q. Okay.</p> <p>6 A. But, yeah.</p> <p>7 Q. And you agree with me that there are laws</p> <p>8 and regulations that relate to mining standards, how</p> <p>9 mining has to be done, things of that nature, correct?</p> <p>10 A. There are -- there's a code of mining</p> <p>11 regulations. To my knowledge, there's not a specific</p> <p>12 code as far as what's required for sampling. It's my</p> <p>13 experience that, essentially, it's based on indications</p> <p>14 from peer-reviewed literature, the concerns the company</p> <p>15 has had as far as maintaining quality of their product,</p> <p>16 so these are the standards that are set. Some companies</p> <p>17 will have, essentially, internal protocols and standards</p> <p>18 that are applied, and they're international companies,</p> <p>19 so this is applied by international.</p> <p>20 Q. So you don't believe there are any</p> <p>21 regulations that relate to any miners that talk about</p> <p>22 requirements of sampling?</p> <p>23 MS. SCOTT: Objection.</p> <p>24 A. At this point, I don't remember. I</p> <p>25 don't --</p>	<p>1 Gy paper, and he talks about running Gy analysis of the</p> <p>2 samples to determine whether or not they're</p> <p>3 representative. Is that a fair sort of, really high</p> <p>4 level synopsis of what he's talking about?</p> <p>5 A. Yes.</p> <p>6 Q. And in forming your opinions, I take it</p> <p>7 you rely -- I mean, we've talked about Gy. You're</p> <p>8 relying on the Gy theory, right? Is it a theory? I</p> <p>9 don't know what the right word to call it is. Is it</p> <p>10 mine theory?</p> <p>11 A. It is an approach.</p> <p>12 Q. Mine approach?</p> <p>13 A. Yeah. It's very dense mathematically.</p> <p>14 Q. I will agree with you there. And you're</p> <p>15 effectively relying on the Gy approach in forming your</p> <p>16 opinions about the mining sampling practices, correct?</p> <p>17 A. It is one of them. It is one approach,</p> <p>18 yes.</p> <p>19 Q. And Afewu and Lewis is another one you</p> <p>20 cite, too?</p> <p>21 A. It's another example.</p> <p>22 Q. And Afewu and Lewis also is another</p> <p>23 mathematical geostatistical computation to determine</p> <p>24 whether or not sampling is adequate and representative,</p> <p>25 correct?</p>
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<p>1 BY MR. FROST:</p> <p>2 Q. "I don't know" is a fine answer, sir.</p> <p>3 A. Yeah. I don't know with certainty.</p> <p>4 Q. Okay. And I think we established this</p> <p>5 morning, you're not a regulatory expert? You're not a</p> <p>6 mine regulations expert?</p> <p>7 A. Yeah.</p> <p>8 Q. Okay. So at this point, you just don't</p> <p>9 know. Have you ever heard of the organization JORC,</p> <p>10 J-O-R-C?</p> <p>11 A. What's that?</p> <p>12 Q. JORC, J-O-R-C. I think it's the Joint</p> <p>13 Regulatory Commission, something like that.</p> <p>14 A. No, I have not.</p> <p>15 Q. Do you recall seeing, in several of the</p> <p>16 Imerys documents, that they were doing sampling to</p> <p>17 various JORAC regulatory specifications?</p> <p>18 A. No, I do not remember seeing that.</p> <p>19 Q. And you have no idea what any of the</p> <p>20 sampling regulations that they're applying for would be?</p> <p>21 That's correct?</p> <p>22 MS. O'DELL: Object to the form.</p> <p>23 A. Yeah. I'm not familiar with that.</p> <p>24 BY MR. FROST:</p> <p>25 Q. While we're talking about Gy, I read the</p>	<p>1 A. Yes. That's another approach.</p> <p>2 Q. Have you actually run any of the</p> <p>3 geostatistical calculations in this case to determine</p> <p>4 whether or not the sampling that was being done by</p> <p>5 Imerys and Johnson & Johnson is adequate?</p> <p>6 MS. SCOTT: Objection.</p> <p>7 A. No, I have not. But I do note that I did</p> <p>8 not see evidence of it either.</p> <p>9 MR. FROST: Move to strike. No question</p> <p>10 was pending.</p> <p>11 BY MR. FROST:</p> <p>12 Q. While we're on mining, let's talk about</p> <p>13 it a little bit. Do you agree with me that mining</p> <p>14 companies do not mill -- sorry. Let me try again. I</p> <p>15 used the wrong word. Do you agree with me that mining</p> <p>16 companies do not drill the entire deposit all at once?</p> <p>17 MS. O'DELL: Object to the form. Do you</p> <p>18 mean --</p> <p>19 BY MR. FROST:</p> <p>20 Q. When they're doing core sampling?</p> <p>21 A. They will -- it depends. So if there's</p> <p>22 field indications that things are looking good and they</p> <p>23 want to establish things, then there would be a reason</p> <p>24 to drill the entire deposit if it's small. But, yeah,</p> <p>25 if you have a large deposit, you would drill that in</p>

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<p style="text-align: right;">Page 214</p> <p>1 phases.</p> <p>2 Q. And you'd sort of do it as the mine</p> <p>3 develops, right, as the -- as you're following the</p> <p>4 deposit? You -- a really untechnical way of saying it</p> <p>5 is, effectively, you're drilling ahead of where you are</p> <p>6 so you know where you can keep going, right?</p> <p>7 MS. SCOTT: Objection.</p> <p>8 A. It -- sometimes it's more complex than</p> <p>9 that. So, basically, people gain investment for</p> <p>10 exploration and it's -- you know, the investors are set</p> <p>11 on doing things one particular way because of what they</p> <p>12 believe. So there's variation in that.</p> <p>13 Q. Okay. And you agree that additional --</p> <p>14 you know, one of the reasons you do additional coring,</p> <p>15 additional drilling, is to further refine the mine plan,</p> <p>16 the mine schedule, things like that?</p> <p>17 A. Yes. So, often, coring will be done</p> <p>18 every day in certain situations. So that's the case in</p> <p>19 some palygorskite deposits in Georgia, and that's also</p> <p>20 the case in Brown Mountain Mine and other, other</p> <p>21 situations, yes. They'll drill daily and produce lots</p> <p>22 of core.</p> <p>23 Q. And, ultimately, mine operators are</p> <p>24 drilling a mine site in order to determine what the ore</p> <p>25 body itself actually looks like, right?</p>	<p style="text-align: right;">Page 216</p> <p>1 factor is the scale of the geologic features that are</p> <p>2 involved in the deposit. So, generally, you want to</p> <p>3 have a core density such that you can capture those</p> <p>4 scales of features.</p> <p>5 Q. And that's ore deposit -- by "ore</p> <p>6 deposit," depending, right, what you have to do to</p> <p>7 capture those features? Effectively, every mine is</p> <p>8 different; is that a fair synopsis?</p> <p>9 MS. SCOTT: Objection.</p> <p>10 A. The -- it depends on the local geology,</p> <p>11 but it still must be representative based on the</p> <p>12 features you're trying to capture.</p> <p>13 BY MR. FROST:</p> <p>14 Q. Okay. I think we're saying the same</p> <p>15 thing. You're just adding a lot more words, right?</p> <p>16 A. Okay.</p> <p>17 Q. But it depends on the local geology what</p> <p>18 the deposit looks like because every deposit is</p> <p>19 different, right?</p> <p>20 MS. SCOTT: Objection.</p> <p>21 A. You can have similar deposits, but, yeah,</p> <p>22 every deposit is in a different location.</p> <p>23 BY MR. FROST:</p> <p>24 Q. Sure. And there are different shapes and</p> <p>25 sizes, right?</p>
<p style="text-align: right;">Page 215</p> <p>1 A. As well as other areas of concern. So I</p> <p>2 gave the example on the Stebbins Hill for Brown</p> <p>3 Mountain. And they, you know, they have extensive</p> <p>4 amounts of core. They filled an entire high school,</p> <p>5 abandoned high school, with core.</p> <p>6 Q. Where you mine -- or sorry. Where you</p> <p>7 drill, when you drill, what angle you're drilling at, et</p> <p>8 cetera, all these are very complicated. You know, in a</p> <p>9 complicated ore body, where you drill, when you drill,</p> <p>10 the angles you drill at, these are all dictated by lots</p> <p>11 of factors, including topography, access to certain</p> <p>12 areas, things of that nature. Do you agree with that</p> <p>13 statement?</p> <p>14 MS. O'DELL: Objection.</p> <p>15 A. Not necessarily. You may -- people want</p> <p>16 to essentially have a good, even distribution so they</p> <p>17 try to drill on a grid, you know, if possible.</p> <p>18 BY MR. FROST:</p> <p>19 Q. Okay. As you said, not necessarily. It</p> <p>20 all depends, sort of, what you're seeing and what you're</p> <p>21 looking for, correct? There's no one way to drill core</p> <p>22 and ore body, right?</p> <p>23 A. There's multiple ways, but, you know,</p> <p>24 using -- essentially having something that is</p> <p>25 representative is reasonable. And one determining</p>	<p style="text-align: right;">Page 217</p> <p>1 A. Yes.</p> <p>2 Q. So because of that, you have to drill</p> <p>3 appropriate to the deposit that you're coring, correct?</p> <p>4 A. Yes.</p> <p>5 Q. And that's a determination that's usually</p> <p>6 made by the on-site geologist or by the company that's</p> <p>7 mining. You know, hopefully, they're consulting with</p> <p>8 somebody who understands the geology to determine where</p> <p>9 to drill. Is that also a fair statement?</p> <p>10 MS. SCOTT: Objection.</p> <p>11 A. Ultimately, the company is responsible</p> <p>12 for how it drills, yes.</p> <p>13 BY MR. FROST:</p> <p>14 Q. Okay. Turn back to page 12 of your</p> <p>15 report. It's the third paragraph. You note that, "The</p> <p>16 practice of hand sorting is not acceptable in the United</p> <p>17 States." Do you have any law or regulation that you're</p> <p>18 pointing to that says that's inappropriate?</p> <p>19 MS. SCOTT: Objection.</p> <p>20 A. No. But, you know, the companies I work</p> <p>21 with wouldn't do that with something of this complexity.</p> <p>22 BY MR. FROST:</p> <p>23 Q. And you've never worked with talc before,</p> <p>24 right? You've never worked with a company that mines</p> <p>25 talc?</p>

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<p>1 A. Correct.</p> <p>2 Q. Okay. The next paragraph down, the -- I</p> <p>3 believe this is an email. Maybe I'll just mark the</p> <p>4 document. It might be easier.</p> <p>5 MR. FROST: We'll mark this one. I think</p> <p>6 we're on 20.</p> <p>7 COURT REPORTER: 20.</p> <p>8 (Exhibit 20 was marked for</p> <p>9 identification.)</p> <p>10 BY MR. FROST:</p> <p>11 Q. Do you see where you are in your report</p> <p>12 on page 12?</p> <p>13 A. I'm checking to see. I'll go back.</p> <p>14 Q. Sorry.</p> <p>15 A. Go back to 12. So 517. Okay.</p> <p>16 Q. And this is -- you're quoting here from</p> <p>17 an email --</p> <p>18 A. Okay.</p> <p>19 Q. -- from Mr. Cutler? Do you see where we</p> <p>20 are?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. So you quote a portion of this</p> <p>23 email from Mr. Cutler, right? And then the next</p> <p>24 paragraph down, you go, "Cutler goes on to say, 'In</p> <p>25 principle, the inspection is enough to guarantee the</p>	<p>1 bottom of 5147 -- I'll go two lines up. I'll start</p> <p>2 there. There's some stuff above it, but it starts,</p> <p>3 "During unloading, a representative industrial sample</p> <p>4 (at least 25mt) is processed in the plant at various</p> <p>5 meshes and sent to our central Denver lab to be analyzed</p> <p>6 for main specs (whiteness, mineralogy, chemical</p> <p>7 composition, major elements and traces). Fibers</p> <p>8 investigation is carried out systematically. The lot is</p> <p>9 quarantined, waiting the lab results." Don't you agree</p> <p>10 with me that's the most important piece of what Cutler</p> <p>11 is saying there --</p> <p>12 MS. SCOTT: Objection.</p> <p>13 BY MR. FROST:</p> <p>14 Q. -- for purposes of your opinion that it</p> <p>15 does not guarantee the absence of fibers or asbestos and</p> <p>16 fibrous talc?</p> <p>17 MS. SCOTT: Objection.</p> <p>18 A. So when the cargo arrives at destination,</p> <p>19 so that's after it's been hand picked, right?</p> <p>20 BY MR. FROST:</p> <p>21 Q. Sure. What I'm saying here is: You use</p> <p>22 the quote you have above as a basis for your --</p> <p>23 A. So they're not -- I'm stating --</p> <p>24 Q. Let me finish, sir.</p> <p>25 A. Okay. I'm sorry. Sorry.</p>
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<p>1 requested specs to insure no fibers.'" And then, after</p> <p>2 that, you make the opinion, "That practice falls below</p> <p>3 the standards of quality control in mining operations in</p> <p>4 the United States, and it does not guarantee the absence</p> <p>5 of fibers, such as asbestos or fibrous talc." Did I</p> <p>6 read that correctly?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. If you look up at the quote from</p> <p>9 Mr. Cutler's email and if you turn to the email itself,</p> <p>10 it's the bottom of page 5147. This is not a complete</p> <p>11 quote from Mr. Cutler's email, correct?</p> <p>12 MS. SCOTT: Objection.</p> <p>13 A. Let me find -- so where is it on 5147?</p> <p>14 BY MR. FROST:</p> <p>15 Q. It's at the bottom.</p> <p>16 MS. SCOTT: It's in B.</p> <p>17 BY MR. FROST:</p> <p>18 Q. Yeah, it's in B.</p> <p>19 A. So "In principle, this inspection is</p> <p>20 enough to guarantee the requested specs and insure no</p> <p>21 fibers."</p> <p>22 Q. Okay. But do you see above that your</p> <p>23 block quote? So what I find interesting is the part you</p> <p>24 left out of Mr. Cutler's email is actually the part that</p> <p>25 talks about the testing for fibers. If you look at the</p>	<p>1 Q. So you use the quote above here as the</p> <p>2 basis for your statement that the practice falls below</p> <p>3 the standards of quality in mine operations in the</p> <p>4 United States and does not guarantee the absence of</p> <p>5 fibers such as asbestos and fibrous talc, but left out</p> <p>6 of the quote you're taking from the email is the</p> <p>7 specific part of the testing that talks about the</p> <p>8 testing for fibers in the talc. Am I correct or</p> <p>9 incorrect?</p> <p>10 A. I did not include that portion in the</p> <p>11 quote.</p> <p>12 Q. Okay. Let's move on.</p> <p>13 A. I --</p> <p>14 Q. All right. Moving on.</p> <p>15 A. Okay.</p> <p>16 MS. SCOTT: If he's not done with his</p> <p>17 answer, let him finish his answer.</p> <p>18 A. But, yeah, I'm not. So it is -- you</p> <p>19 know, if you're mining material and then you have a</p> <p>20 point of shipment, you would want to test that at that</p> <p>21 point of shipment in case you find something later. You</p> <p>22 would be able to identify where in the supply chain an</p> <p>23 issue occurred. So is this -- you know, is this shipped</p> <p>24 by a ship, correct? Right? So multiple things can be</p> <p>25 put into a ship cargo. You can have a whole crate of</p>

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<p>1 asbestos, you know, from Indiana or Russia or some other</p> <p>2 place or some other material that is mixed in. So, to</p> <p>3 me, it really does make sense that at the stage of when</p> <p>4 it leaves the port, you would want to have some quality</p> <p>5 control so --</p> <p>6 BY MR. FROST:</p> <p>7 Q. Here's my question. Isn't that exactly</p> <p>8 the part that you left out of the quote? Isn't it</p> <p>9 disingenuous that you left out the fibrous talc?</p> <p>10 A. As I read it, as I read it --</p> <p>11 MS. O'DELL: Dr. Krekeler, he's not done.</p> <p>12 A. Oh, I'm sorry. Sorry.</p> <p>13 BY MR. FROST:</p> <p>14 Q. Don't you agree with me that it's</p> <p>15 disingenuous to leave out the specific portion of the</p> <p>16 quote that talks about the testing that's done once the</p> <p>17 talc arrives at port in Houston when you're making,</p> <p>18 based on that quote, the opinion that it does not</p> <p>19 guarantee the absence of fibers and falls short?</p> <p>20 MS. SCOTT: Objection. Misrepresents.</p> <p>21 A. Yeah. I say it's in the report for the</p> <p>22 reasons I provided.</p> <p>23 BY MR. FROST:</p> <p>24 Q. Okay. All right. Let's move on.</p> <p>25 MR. FROST: Actually, if you want, I</p>	<p>1 A. Yes.</p> <p>2 Q. Okay. What is the basis that grinding</p> <p>3 the sample before testing will make it much more</p> <p>4 difficult to --</p> <p>5 A. So talc is a phyllosilicate mineral.</p> <p>6 It's a two-to-one layer clay. Essentially, the</p> <p>7 structure is held together by long hydrogen bonds and it</p> <p>8 is mechanically very soft. So, basically,</p> <p>9 phyllosilicates have essentially delicate structures and</p> <p>10 they need to be prepared in specific ways so grinding is</p> <p>11 a rotary motion and what that does is -- the crystal</p> <p>12 structure is shown here for talc.</p> <p>13 So what that does is it takes these</p> <p>14 two-to-one layers. When you grind, you displace, you</p> <p>15 know, essentially, a rotation of the crystal structure,</p> <p>16 and that rotation of the crystal structure basically</p> <p>17 destroys the crystallographic coherency through the clay</p> <p>18 particle. So if you are -- essentially, for x-ray</p> <p>19 analysis, you're supposed to crush materials. So crush</p> <p>20 is specifically an up-and-down motion. And, basically,</p> <p>21 it's easy to do with talc. You crush it in this</p> <p>22 up-and-down motion, typically in an agate mortar and</p> <p>23 pestle.</p> <p>24 And then so, basically, what happens is</p> <p>25 you also have other potential contaminants such as</p>
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<p>1 don't know how long we've been going. This is</p> <p>2 probably a good time for a break. I'm changing</p> <p>3 subjects.</p> <p>4 MS. SCOTT: Sure. Great.</p> <p>5 VIDEOGRAPHER: We are now going off</p> <p>6 record. The time is 4:12.</p> <p>7 (A recess was taken from 4:12 to 4:38.)</p> <p>8 VIDEOGRAPHER: We're now back on record,</p> <p>9 and the time is 4:38.</p> <p>10 BY MR. FROST:</p> <p>11 Q. I'm going to move back to page 12 --</p> <p>12 A. Okay.</p> <p>13 Q. -- of your report. The last full</p> <p>14 paragraph on page 12, sir, it's a document entitled</p> <p>15 "Quality Control."</p> <p>16 A. Okay.</p> <p>17 Q. Okay. And you note, "This document</p> <p>18 includes procedures related to Guangxi Number 1 and</p> <p>19 Number 2A, the talc ore purchased by Defendants for use</p> <p>20 in Johnson's Baby Powder and Shower to Shower products.</p> <p>21 Again, the procedure calls for samples to be ground</p> <p>22 prior to testing a protocol that will disrupt the</p> <p>23 physical properties of the talc ore, making detection of</p> <p>24 harmful contaminants, including asbestos, much more</p> <p>25 difficult." Did I read that right?</p>	<p>1 chrysotile. Chrysotile is a one-to-one layer</p> <p>2 serpentine. It is coiled because the octahedral sheet</p> <p>3 and the tetrahedral sheet don't match up. So there's</p> <p>4 other serpentines such as antigorite, lizardite,</p> <p>5 crocidolites, other things like that.</p> <p>6 So what needs to happen is, again, that</p> <p>7 needs to be prepared in a crush method, not a rotary,</p> <p>8 not ground. So grinding -- ground, grinding -- those</p> <p>9 words have specific meanings in the context of</p> <p>10 phyllosilicates. It's been well, recognized, and I</p> <p>11 provide several references elsewhere in the report.</p> <p>12 So essentially what happens is x-ray</p> <p>13 diffraction has detection limits, and for many</p> <p>14 materials, such as quartz, that are very crystalline,</p> <p>15 your detection limit is approximately about a tenth of a</p> <p>16 weight percent, and that's generally understood. That's</p> <p>17 a long-standing detection limit.</p> <p>18 Clay minerals, in general, the</p> <p>19 phyllosilicates, in general, those materials typically</p> <p>20 have a detection limit that is at least a few weight</p> <p>21 percent, in part because they start off as essentially</p> <p>22 poorly crystalline material. So if you take a talc or a</p> <p>23 chlorite and you compare that to another, you know, a</p> <p>24 mineral such as a pyroxene, the overall crystallinity of</p> <p>25 the pyroxene is much, much more than the talc or the</p>

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<p>1 chlorite. So and then there's also many issues with --</p> <p>2 the minerals are just very sensitive, and they naturally</p> <p>3 have disorder.</p> <p>4 For example, chlorite theoretically can</p> <p>5 have 1,024 different arrangements of the layers of atoms</p> <p>6 in the structure, two-layer structure. So, basically,</p> <p>7 the crushing and grinding, you can grind -- if you have,</p> <p>8 let's say you have 4 percent chrysotile and 96 percent</p> <p>9 talc and you have that sample and you grind it, and</p> <p>10 essentially, you are destroying the crystal structures</p> <p>11 of both, and you only have, essentially, a 1 percent or</p> <p>12 so that is still crystalline or maybe none of it is</p> <p>13 crystalline.</p> <p>14 You can grind, actually do experiments</p> <p>15 and grind things to be amorphous. We did this when I</p> <p>16 was a Ph.D. student. He had us hammer home the point.</p> <p>17 But, basically, so the net effect is is when you grind</p> <p>18 stuff, you deflate the detection limit of materials that</p> <p>19 are there.</p> <p>20 It's already a problem -- you know,</p> <p>21 chrysotile is already problematic because, essentially,</p> <p>22 the shape of it. So it's a difficult material to work</p> <p>23 with. When you grind those materials, you will end up</p> <p>24 with, essentially, stuff that won't diffract. So,</p> <p>25 therefore, with powder x-ray diffraction, you cannot be</p>	<p>1 crush and smear, correct?</p> <p>2 MS. O'DELL: Objection.</p> <p>3 A They would be far less -- I think the</p> <p>4 proper thing to say is they would be far less</p> <p>5 susceptible to reduction and crystallinity, but, yeah,</p> <p>6 the chrysotile would be.</p> <p>7 BY MR. FROST:</p> <p>8 Q Okay. But, again, chrysotile is not --</p> <p>9 because of the closeness to talc, XRD is not the primary</p> <p>10 way of identifying chrysotile, correct?</p> <p>11 A. Oh, no.</p> <p>12 Q. I'm talking about specific to talc here.</p> <p>13 A. Were -- I'm sorry, was the question can</p> <p>14 you -- the difference --</p> <p>15 Q. Not can you, no.</p> <p>16 A. -- between talc and chrysotile?</p> <p>17 Q. Okay. Let me ask it another way. In the</p> <p>18 testing that is done of talc to determine whether or not</p> <p>19 there is asbestos, the way -- the test for chrysotile,</p> <p>20 you'll agree with me, is PLM, correct?</p> <p>21 A. I understand that powder x-ray</p> <p>22 diffraction is the primary screen.</p> <p>23 Q. That's the first screen, correct?</p> <p>24 A. Yes.</p> <p>25 Q. Okay.</p>
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<p>1 assured that what you're measuring that you detect. So</p> <p>2 that's the issue with grounding.</p> <p>3 Q. Okay. So let me start here. Amphibiles</p> <p>4 aren't phyllosilicates, correct, amphibole minerals?</p> <p>5 MS. O'DELL: Amphiboles.</p> <p>6 BY MR. FROST:</p> <p>7 Q. Or amphiboles.</p> <p>8 A. They're part of the biopyriboles.</p> <p>9 Q. Okay.</p> <p>10 A. So but they are not a --</p> <p>11 Q. It's not phyllosilicate, correct?</p> <p>12 A. Correct.</p> <p>13 Q. And, again, the point of XRD, the</p> <p>14 testing, is to determine whether or not there are</p> <p>15 amphibole particles in the talc. Is that also correct?</p> <p>16 MS. SCOTT: Objection.</p> <p>17 A. Yes.</p> <p>18 BY MR. FROST:</p> <p>19 Q. Okay. So what you're talking about here</p> <p>20 is we'd ruin the talc and it would be hard, but we don't</p> <p>21 care because we know talc is in there. What we're</p> <p>22 looking for are amphiboles, right? So crushing isn't</p> <p>23 going to be a problem with identifying the amphiboles,</p> <p>24 because they aren't subject to smear and amorphousness,</p> <p>25 if that's the right word, but becoming amorphous through</p>	<p>1 A. And then if -- then if there's something</p> <p>2 that's detected, it then goes to PLM. And then if is</p> <p>3 something is detected, it goes to TEM. So if you</p> <p>4 don't -- if you're not -- if you're having, essentially,</p> <p>5 a false negative because you've ground away the</p> <p>6 chrysotile, you would not -- you know, as things were</p> <p>7 described, you wouldn't go on to the other techniques,</p> <p>8 but you would potentially have tremolite.</p> <p>9 Q. Yes. And you're actually going -- again,</p> <p>10 you've looked at Longo's testing, right?</p> <p>11 A. Yes.</p> <p>12 Q. So would you invalidate Longo's testing</p> <p>13 because he crushes and grinds the samples before putting</p> <p>14 them through his various tests, including XRD?</p> <p>15 MS. O'DELL: Objection.</p> <p>16 A. I -- there might be some differences, but</p> <p>17 overall, my review of Longo's report, I think it's fine.</p> <p>18 BY MR. FROST:</p> <p>19 Q. Okay. And, again, in looking through</p> <p>20 Longo's report, despite that he crushed and smeared, did</p> <p>21 he come up with any amorphous -- you know, did he</p> <p>22 identify any amorphous figures within the talc?</p> <p>23 MS. SCOTT: Objection.</p> <p>24 MS. O'DELL: Object to form.</p> <p>25 A. I don't remember specific. I remember</p>

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<p>1 seeing lots and lots of TEM images by -- there's a lot 2 of TEM images. I don't remember specifically. 3 BY MR. FROST: 4 Q. You also agree with me that the amphibole 5 content that you're looking for in baby powder is 6 actually very small. We're talking about the micron 7 level, correct? 8 MS. O'DELL: Object to the form. 9 A. I'm sorry. What? 10 BY MR. FROST: 11 Q. We're talking about particles that are 12 measured by microns, not -- 13 A. For? 14 Q. -- inches or centimeters for the -- 15 A. For what context? 16 Q. The amphiboles -- 17 A. The amphiboles? 18 Q. -- that would be located in ground talcum 19 powder. 20 A. I'm sorry. I'm unclear on the question. 21 Can I -- 22 Q. I'll just ask it again. 23 A. Well, I would prefer to read, if that's 24 okay. 25 Q. Well, I'd prefer to reask you the, ask</p>	<p>1 or done by anybody else, have you ever seen any problem 2 with either smear or amorphous? 3 MS. SCOTT: Object to the form. 4 A. Yeah. By the nature of the test, as it's 5 been described, you know, you can't, you can't see -- I 6 want to say you can't see something that is not, that 7 you can't detect. So amorphous material doesn't 8 diffract x-rays. So x-rays arise when we have coherent 9 crystallinity that occurs. And then I'm trying to -- 10 BY MR. FROST: 11 Q. I understand, but let me stop you there. 12 You would see amorphous on TEM or SEM, wouldn't you, 13 when you were looking at images of the talc after it's 14 been prepared for a sample? 15 MS. O'DELL: Objection. 16 A. The -- only if you're, only if you're 17 looking for it. So you need to have electron 18 diffraction data that -- you said if you're only looking 19 for the asbestos materials so you're looking for 20 crystalline materials. You would not necessarily be 21 looking for amorphous. So I don't think Longo was 22 tasked with finding amorphous, amorphous 23 phyllosilicates. I think he -- 24 BY MR. FROST: 25 Q. But I'm confused. Doesn't Longo</p>
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<p>1 you a different question, sir. 2 A. Okay. All right. Good. 3 MS. O'DELL: He can ask a different 4 question. 5 BY MR. FROST: 6 Q. So, again, my question is: The 7 amphiboles that we care about here, the ones we're 8 finding in the testing of talcum powder, are in microns 9 of size. They're tiny, correct? 10 A. They can be, yes. 11 Q. Okay. And because they're so small and 12 small by volume, grinding and crushing really isn't a 13 problem because you're not going to affect the 14 crystalline structure of something that small when you 15 grind it. Do you also agree with that? 16 MS. SCOTT: Objection. 17 A. Not necessarily. It depends on the 18 specific methods of grinding. 19 BY MR. FROST: 20 Q. And have you seen any evidence in any of 21 the testing that you've looked at in this case that 22 grinding and crushing has caused a problem with smear or 23 amorphous -- I guess it would become an amorphous 24 particle. I don't know what the right second term would 25 be. But in any of the testing you've seen done by Longo</p>	<p>1 categorize every particle that was on the TEM grids? 2 MS. O'DELL: Objection. In what way? 3 MR. FROST: He accounts for them on his 4 count sheets. 5 BY MR. FROST: 6 Q. If you don't know, sir, that's fine, too. 7 A. I don't remember. 8 Q. Okay. That's fine. We'll move on. 9 Now, sir, are you aware that talcum 10 powder, cosmetic talcum powder specifically is regulated 11 by the FDA? 12 MS. SCOTT: Objection. 13 A. I know they have looked at it. I don't 14 know if they've -- I'm not a regulatory expert. So I 15 just know that they've looked at it. I don't know that 16 there's a study on talc. 17 BY MR. FROST: 18 Q. I'm not talking about regulations, 19 regulations and testings -- 20 A. Oh, okay. I'm sorry. Yeah. No. 21 Q. Okay. All right. Are you aware that 22 there is an FDA sanction testing model called J4-1? 23 A. No, I'm not. 24 Q. Okay. And you don't know whether or not 25 the companies are using J4-1 to test their product</p>

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<p>1 because that's what's required of them?</p> <p>2 MS. O'DELL: Object to form.</p> <p>3 MS. SCOTT: Object to the form.</p> <p>4 A. No.</p> <p>5 BY MR. FROST:</p> <p>6 Q. Okay. Sir, do you agree with me that</p> <p>7 compliance with legal standards is an important</p> <p>8 consideration in determining if a mine is being operated</p> <p>9 correctly?</p> <p>10 MS. SCOTT: Objection.</p> <p>11 A. Yes, in general.</p> <p>12 BY MR. FROST:</p> <p>13 Q. And as we said before, you just don't</p> <p>14 know one way or the other whether or not -- well, I</p> <p>15 guess, what regulations govern these talc mines and</p> <p>16 whether or not the companies were abiding by those</p> <p>17 regulations. Is that fair?</p> <p>18 MS. SCOTT: Object to the form.</p> <p>19 BY MR. FROST:</p> <p>20 Q That's not your area of expertise?</p> <p>21 A. Yeah. I'm not a regulatory expert.</p> <p>22 Q. Turn to page 39, I believe, of your</p> <p>23 report. One, two, third paragraph down, it says,</p> <p>24 "Examination of data from several mines."</p> <p>25 A. On page 39. "Examination of data from</p>	<p>1 for that statement, correct?</p> <p>2 A. Yes.</p> <p>3 Q. So we'll start at the first cite, which</p> <p>4 is Furtron or Furcron, F-u-r-c-r-o-n, and others, 1947,</p> <p>5 deposits of Murray -- talc deposits in Murray County,</p> <p>6 Georgia, Georgia State Division of Conservation</p> <p>7 Department of Mines, Mineralogy, Mining and Geology?</p> <p>8 A. Uh-huh.</p> <p>9 Q. Okay. You agree with me that they're</p> <p>10 looking at Georgia mine formations, correct?</p> <p>11 A. Yes.</p> <p>12 Q. And that would -- they'd have nothing --</p> <p>13 no opinions or no specifics of what the actual ore body</p> <p>14 in Vermont looks like or Italy or China, correct?</p> <p>15 MS. SCOTT: Objection.</p> <p>16 A. Correct.</p> <p>17 BY MR. FROST:</p> <p>18 Q. Okay. The second citation here is Berg</p> <p>19 1977, and I think that was the one we identified earlier</p> <p>20 that was a mis-cite?</p> <p>21 A. Yes. I think it relates to Montana.</p> <p>22 Q. All right. Tab -- the next one is</p> <p>23 Mark -- where is it? Sandrone and Zucchetti?</p> <p>24 A. So --</p> <p>25 (Exhibit 21 was marked for</p>
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<p>1 several mines," that paragraph?</p> <p>2 Q. Yes, that paragraph. Let me just orient</p> <p>3 myself. I apologize.</p> <p>4 All right. You note here, "Examination</p> <p>5 of data from several mines shows that ore bodies are</p> <p>6 very complex, with mixtures of several rock types,</p> <p>7 including those likely to have the presence of asbestos</p> <p>8 and heavy metals. These rock types are intimately mixed</p> <p>9 with talc ore. The variation of the bodies of rock</p> <p>10 differs and significant features may be only one foot</p> <p>11 thick or less." Correct?</p> <p>12 A. Yes. That is what it says.</p> <p>13 Q. Are you talking about the features there</p> <p>14 of the talc ore itself or are you talking about the</p> <p>15 other minerals that might be in the geological</p> <p>16 formation?</p> <p>17 A. So I'm talking about the ore as a whole,</p> <p>18 including, you know, lithologies that are rich in talc</p> <p>19 and not as well as the minerals and all the constituents</p> <p>20 of ore.</p> <p>21 Q. So you're talking about the ore body? I</p> <p>22 just want to clarify what we're talking about there.</p> <p>23 All right.</p> <p>24 A. Yes.</p> <p>25 Q. And that's Footnote 36, is the support</p>	<p>1 identification.)</p> <p>2 BY MR. FROST:</p> <p>3 Q. So it seems like this is talking about</p> <p>4 the Italian deposit.</p> <p>5 A. Yes. So, yeah.</p> <p>6 Q. You go one, two, three, four.</p> <p>7 MR. FROST: Oh, I apologize I thought he</p> <p>8 had the paper in front of him.</p> <p>9 COURT REPORTER: No.</p> <p>10 MR. FROST: Oh, I'm sorry.</p> <p>11 BY MR. FROST:</p> <p>12 Q. I'll reask the question. She didn't get</p> <p>13 it.</p> <p>14 So the question was: This paper appears</p> <p>15 to be dealing with the Italian mines, correct, the</p> <p>16 Italian deposit?</p> <p>17 A. Yes. Can I state a clarification?</p> <p>18 Q. Sure.</p> <p>19 A. So this is actually meant as an</p> <p>20 introduction paragraph. So several mines, meaning</p> <p>21 several mines of talc, in general.</p> <p>22 Q. Okay.</p> <p>23 A. So that sentence does not specifically</p> <p>24 relate to -- as written doesn't necessarily relate to</p> <p>25 mines in Vermont but just in general.</p>

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<p>1 Q. Okay.</p> <p>2 A. So --</p> <p>3 Q. So it's not a statement --</p> <p>4 A. The thing that's gone, the Berg paper</p> <p>5 shows really intimate associations of, you know,</p> <p>6 small-scale features. So it's meant to be general.</p> <p>7 Sorry.</p> <p>8 Q. Okay. So these aren't talking about any</p> <p>9 of the mines that we're specifically talking about here:</p> <p>10 The Vermont mines, the Italian mine and the Chinese</p> <p>11 mines, the ones at issue on page 7 and 8 --</p> <p>12 A. That sentence does --</p> <p>13 Q. -- of your report?</p> <p>14 A. -- not refer to those, yes.</p> <p>15 Q. Turn to page 41 of your report, please.</p> <p>16 The very -- the sentence that goes from 41 to 42.</p> <p>17 "Composite sampling is a flawed methodology to</p> <p>18 adequately" monitor -- sorry. It's a typo, but --</p> <p>19 "adequately monitoring for asbestos and toxic metals and</p> <p>20 should be reserved for products not intended for human</p> <p>21 consumption or cosmetic use." And then you cite to the</p> <p>22 Afewu paper?</p> <p>23 A. That is an editorial error. The Afewu</p> <p>24 reference is there as its own parenthetical sentence.</p> <p>25 Q. So you agree with me --</p>	<p>1 A. No, I did not.</p> <p>2 Q. Do you know if your counsel provided the</p> <p>3 charts that you created to Dr. Cook?</p> <p>4 MS. SCOTT: Objection.</p> <p>5 A. I don't know if they did or not. I</p> <p>6 presume not. He looked at the same -- I think he looked</p> <p>7 at the same sets of documents. It doesn't surprise me</p> <p>8 that --</p> <p>9 BY MR. FROST:</p> <p>10 Q. That they look exactly the same?</p> <p>11 A. -- they're similar. I don't know if</p> <p>12 they're exactly the same. I didn't --</p> <p>13 Q. Yeah. You didn't look at it in detail?</p> <p>14 A. -- look at Cook's. I didn't look at</p> <p>15 Cook's documents in detail.</p> <p>16 Q. Bear with me a second. I have to go to</p> <p>17 the third box. It's far away.</p> <p>18 (Exhibit 22 was marked for</p> <p>19 identification.)</p> <p>20 VIDEOGRAPHER: I'm going to make a</p> <p>21 general housekeeping announcement. If you've</p> <p>22 got a laptop in front of you and you've got a</p> <p>23 mic on, push it back a little bit and make sure</p> <p>24 your phones stay away from the mic wires.</p> <p>25 Thanks.</p>
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<p>1 A. I don't -- it's a typo.</p> <p>2 Q. Okay. So you agree with me that Afewu</p> <p>3 and Lewis don't talk about testing for heavy metals or</p> <p>4 whether or not ores are meant for human consumption?</p> <p>5 A. Correct, yeah. That's a streaming, a</p> <p>6 streaming reference. It's cited where -- it's just</p> <p>7 stand alone. There's a period before it and a period</p> <p>8 after it. Sorry about that.</p> <p>9 Q. That's okay. All right. I'm going to</p> <p>10 turn to the various charts now that are in your report.</p> <p>11 So as a preliminary question, did you review each of the</p> <p>12 documents that are listed in the various documents?</p> <p>13 A. I looked at all these documents, yes.</p> <p>14 Q. Have you ever seen the expert report done</p> <p>15 by Dr. Cook in this case?</p> <p>16 A. Yeah. I have seen it recently, yes.</p> <p>17 Q. It was after you were done drafting your</p> <p>18 initial and supplemental reports? Do you know?</p> <p>19 A. I believe so.</p> <p>20 Q. Okay. I'll note that Dr. Cook seems to</p> <p>21 have the exact same lists that you do. Did you provide</p> <p>22 these to him?</p> <p>23 A. We looked at the same data. I'm sorry.</p> <p>24 Q. Okay. I was going to say, did you</p> <p>25 provide the charts that you created to him?</p>	<p>1 MR. FROST: Can we go off the record for</p> <p>2 a second?</p> <p>3 VIDEOGRAPHER: We're now going off</p> <p>4 record. The time is 5:02.</p> <p>5 (Off the record.)</p> <p>6 VIDEOGRAPHER: We are now back on record,</p> <p>7 and the time is 5:10.</p> <p>8 BY MR. FROST:</p> <p>9 Q. All right, sir. If you look at page 21</p> <p>10 of your report, do you see the sample with the date</p> <p>11 8/22/1985?</p> <p>12 VIDEOGRAPHER: I'm sorry, Counsel. Can</p> <p>13 you put that notebook lid down?</p> <p>14 MR. FROST: Oh.</p> <p>15 VIDEOGRAPHER: Thanks.</p> <p>16 MS. O'DELL: 21.</p> <p>17 A. 21, and what was the line on the table?</p> <p>18 BY MR. FROST:</p> <p>19 Q. 8/22/1985.</p> <p>20 A. Yes.</p> <p>21 Q. I'll move this binder, so it's out of the</p> <p>22 way.</p> <p>23 And that relates to sample WMI 85-28 and</p> <p>24 WMI 85-30?</p> <p>25 A. Yeah, as indicated on the chart.</p>

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<p>1 Q. Do you know where Samples 85-28 and 85-30 2 were mined? 3 A. I'm looking at the document. 4 Q. Yes. If you look for the actual 5 document, if you turn to Tab 1 in the book you have 6 there. 7 A. I have Tab 1. 8 Q. All right. Great. 9 A. All right. Let me just read. Yes. As 10 is common, there's not -- it doesn't say the exact 11 location. 12 Q. Would it surprise you to learn that these 13 samples came from a mine in San Andreas, California? 14 MS. SCOTT: Objection. 15 A. I did not know that. 16 BY MR. FROST: 17 Q. Turn to Tab 2. It's a document Bates 18 stamped JNJ 65646. 19 A. I'm sorry. Tab 2? 20 Q. Yeah. Turn to the second page. 21 A. Okay. The second page. 22 Q. Okay. And if you look at sample WMI 23 85-28, it notes that it's grade TC-700. Do you see 24 that? 25 A. 85-28. Oh, okay. Yes.</p>	<p>1 A. Presumably, yeah. 2 BY MR. FROST: 3 Q. On page 12, if you go down to the next 4 sample listed, it's the 4/29/1986 sample. 5 A. I'm sorry. Page 12? 6 Q. I'm sorry. I meant page 21. I got it 7 backwards. 8 A. Page 21. Okay. And I'm sorry. And what 9 was the line? 10 Q. It's the next one down, 4/29/1986. 11 A. 4/29/1986. So J&J 182. So is that -- 12 Q. That's Tab 4. 13 A. Tab 4. 14 Q. And do you see in the middle of page 15 we're talking here, it's sample number WMI 85-53, WMI 16 85-55 and WMI 85-57? 17 A. Yes. 18 Q. Okay. And those are the ones that 19 they're talking about in the letter about the chrysotile 20 detection? 21 A. Yes. 22 Q. Okay. Do you know where these samples 23 were mined? 24 A. We can just check. No. 25 Q. Turn to Tab 5, sir. And that's the</p>
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<p>1 MS. O'DELL: What sample are you on in 2 the chart, Jack? I'm sorry. 3 MR. FROST: It's WMI 85-28. It's on page 4 2. 5 MS. O'DELL: I've got you. All right. 6 BY MR. FROST: 7 Q. And then looking down at 85-30, which is 8 the second sample, that is also grade TC-700, correct? 9 A. Correct. 10 Q. Okay. And those are the two samples we 11 saw from the Tab 1 document that appear in the chart, 12 right? 13 A. Yes. 14 Q. Okay. You now can turn to Tab 3, which 15 is a document that starts IMERYS 013723. If you turn to 16 the third page of it. The very bottom of the product 17 certification protocol on page 3. Yeah, I know. It's 18 tiny. I apologize. Do you see where it says, "San 19 Andreas, California, Red Hill Grade," and then it has 20 "TC-700, light" and "dark"? 21 A. Yes. 22 Q. Okay. This clearly indicates that these 23 two samples did not come from one of the Vermont mines 24 or the Italian or the Chinese mines, correct? 25 MS. SCOTT: Object to the form.</p>	<p>1 document with Bates number JNJ 578888. You can turn to 2 the third page. 3 A. Where is that on the -- 4 Q. It's on the -- 5 A. Chart? 6 Q. No. It's the -- I was just identifying 7 for the record the document. It's Tab 5 of the binder. 8 A. Tab 5, yes. 9 Q. If you turn to the third page -- 10 MS. SCOTT: 8890. 11 BY MR. FROST: 12 Q. Yeah, 8890. 13 A. Yes. 14 Q. Okay. Do you see here on here the WMI 15 85-53 is identified as the grade TC-700? 16 A. Yes. 17 Q. And that's the one we just saw that comes 18 from the San Andreas, California, mine, correct? 19 A. Okay. Yes. 20 Q. If you look down at WMI 85-56 and 85-57, 21 which are the other two samples, do you see that one is 22 grade 76 and the other is also grade TC-700? 23 A. Yes. 24 Q. Okay. So for the TC-700, we know that's 25 San Andreas. If you turn back to Tab --</p>

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<p>1 MS. O'DELL: Object to the form.</p> <p>2 BY MR. FROST:</p> <p>3 Q. Turn back to Tab 3.</p> <p>4 MS. O'DELL: Is that a question?</p> <p>5 MR. FROST: Sure.</p> <p>6 BY MR. FROST:</p> <p>7 Q. Do you agree with me that we know from</p> <p>8 looking at the document before that the TC-700 is</p> <p>9 identified as San Andreas, California?</p> <p>10 MS. O'DELL: Object to the form.</p> <p>11 A. I don't remember.</p> <p>12 BY MR. FROST:</p> <p>13 Q. We're going to turn back there. It's Tab</p> <p>14 3, please, in the binder. It's the last page of that</p> <p>15 document.</p> <p>16 A. Right. Oh, okay. Yeah.</p> <p>17 Q. And do you also see the grade 76?</p> <p>18 A. 76 is listed there as well.</p> <p>19 Q. Okay.</p> <p>20 A. Okay. Yes.</p> <p>21 Q. So the samples in this, from this testing</p> <p>22 also did not come from any of the mines utilized by</p> <p>23 Johnson & Johnson for talcum powder, correct?</p> <p>24 MS. O'DELL: Object to the form.</p> <p>25 A. Okay. As far as -- yeah.</p>	<p>1 A. No, not specifically.</p> <p>2 Q. Okay. If you turn to Tab 7, that's the</p> <p>3 document, it's identified as JNJMX68_2659.</p> <p>4 A. JNJMX68_2659. Okay. Where is it in</p> <p>5 the --</p> <p>6 Q. If you look at the third paragraph.</p> <p>7 A. Okay.</p> <p>8 Q. So it's the third and the fifth</p> <p>9 paragraph.</p> <p>10 A. "The samples represented both the</p> <p>11 industrial materials produced at the Gassetts and West</p> <p>12 Windsor."</p> <p>13 Q. Okay. If you look down at the fifth</p> <p>14 paragraph, it says, "In one instance, asbestos was</p> <p>15 identified, this being associated with sample D-GI</p> <p>16 produced at the Gassetts Mill."</p> <p>17 A. Okay.</p> <p>18 Q. And do you agree with me that the</p> <p>19 Gassetts Mill and industrial talc are different than the</p> <p>20 cosmetic talcum powder used in Johnson & Johnson Baby</p> <p>21 Powder -- or Johnson's Baby Powder and Shower to Shower</p> <p>22 products?</p> <p>23 A. The geology is related.</p> <p>24 Q. Okay. But specifically the -- this is</p> <p>25 not talcum powder that ever made it into a bottle of</p>
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<p>1 BY MR. FROST:</p> <p>2 Q. Turn to page 19 of your report.</p> <p>3 A. Page 19 of the report?</p> <p>4 Q. Yes. The very bottom, the</p> <p>5 10/10/1974 sample.</p> <p>6 A. Okay.</p> <p>7 Q. And if you look at Tab 7, that's the</p> <p>8 corresponding document. I'm sorry. Tab 6. I</p> <p>9 apologize. Tab 6 is the corresponding document.</p> <p>10 A. J&J-74. Okay.</p> <p>11 Q. Do you see here where it states that the</p> <p>12 sample that came back, the fibrous asbestiform material</p> <p>13 is D-GI? It's in the semi-highlighted section, the gray</p> <p>14 box.</p> <p>15 A. "Only one sample was found to contain</p> <p>16 fibrous asbestiform material."</p> <p>17 Q. And that's D-GI?</p> <p>18 A. D -- okay. If you say -- all right.</p> <p>19 Okay. "7/15 to 7/29. Chrysotile fibers were found to</p> <p>20 be present at an estimated level (good at approximately</p> <p>21 to an order of magnitude) of .006 percent."</p> <p>22 Q. And do you know where this sample was</p> <p>23 mined?</p> <p>24 A. Not specifically, no. I mean it's --</p> <p>25 Q. That -- yeah, I think it's the short --</p>	<p>1 Johnson's Baby Powder or Shower to Shower; is that</p> <p>2 correct?</p> <p>3 MS. SCOTT: Objection.</p> <p>4 A. Presumably, that is correct.</p> <p>5 BY MR. FROST:</p> <p>6 Q. Turn to page 15 of your report.</p> <p>7 A. Page 15?</p> <p>8 Q. Yep.</p> <p>9 A. Of the report? Okay.</p> <p>10 Q. It's the sample 7/7/1971.</p> <p>11 A. 7/7/1971, J&J-15, Colorado School of</p> <p>12 Mines, the Vermont talc.</p> <p>13 Q. And if you turn to Tab 8. This is the</p> <p>14 corresponding document related to processed talc sample</p> <p>15 344-L?</p> <p>16 MS. O'DELL: I'm sorry, Jack. Did you</p> <p>17 say Tab 8?</p> <p>18 MR. FROST: Tab 8 of the binder, yes.</p> <p>19 It's JNJAZ55_6089.</p> <p>20 MS. O'DELL: Great. Thanks.</p> <p>21 A. It says, "only minor amounts (below</p> <p>22 1 percent) of tremolite and actinolite were detected."</p> <p>23 BY MR. FROST:</p> <p>24 Q. Okay. And you agree that this is sample</p> <p>25 344-L that they're talking about?</p>

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<p>1 A. Yeah. It says, "Following are results of 2 the x-ray analyses on the 344-L Vermont talc product and 3 the six monthly Vermont talc product samples." Yes. 4 MS. O'DELL: Jack, are you going to 5 mark -- I think what made it to the chart was 6 J&J-15. 7 MR. FROST: I didn't have a copy with the 8 J&J-15 sticker on it. It's the same document, 9 though. This is just from our production. 10 MS. O'DELL: I see. Do you mind giving 11 me just a minute to pull that up -- 12 MR. FROST: Sure. 13 MS. O'DELL: -- so we can correlate it? 14 It will take me two seconds. 15 Thanks very much. 16 BY MR. FROST: 17 Q. If you turn, sir, to page -- or, sorry, 18 to Tab Number 9. Well, before I get there, this report 19 was done by the Colorado School of Mines, correct? 20 A. Colorado School of Mines Research 21 Institute it what it says, yes. 22 Q. Are you aware that the Colorado School of 23 Mines issued a subsequent report regarding these 24 samples? 25 A. I don't know. I believe I've seen other</p>	<p>1 permissible, but, again, you know, it also indicates 2 that they're sloppy with their materials and they -- 3 Q. I'll stop you here. Without speculating, 4 you can't tell me that the talc in 344-L contained 5 asbestos, correct? 6 MS. SCOTT: Object to the form. 7 A. I would say that based on these 8 documents, that, objectively, the analysis might be 9 suspect or based on what I saw previously. 10 BY MR. FROST: 11 Q. Yeah. But you can't tell me one way or 12 the other based on this, considering it's a retraction? 13 A. Well, it was measured once. We don't 14 know -- they didn't -- I don't see any data that backs 15 up -- 16 Q. Well, there's no data in this report. 17 A. It says, I saw where evidently 18 contamination. "Evidently" is a word up to 19 interpretation. Prove it. I don't see, you know, 20 essentially, some sort of chemical analysis or whatever 21 that would prove the exact same thing. 22 Q. So with the guy who did the testing 23 saying my testing is wrong, you're still comfortable in 24 saying 100 percent that there was asbestos in that 25 talcum powder sample?</p>
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<p>1 things from the Colorado School of Mines. 2 Q. Okay. If you turn to Tab 9. It's a 3 document identified as JNJAZ55_3828. 4 A. Okay. 5 Q. Do you see it where it says -- it's Point 6 Number 1. "In the report of July 7, 1971." Do you 7 agree with me that's the report you just looked at in 8 Tab 8? 9 A. Okay. 10 Q. Continues down, it says, "Subsequent 11 x-ray work on the six monthly product samples and the 12 344-L product sample shows no definite indications of 13 asbestos-type minerals within our limits of 14 detectability. The trace amounts I saw were evidently 15 contamination from the standard asbestos samples." Did 16 I read that correctly? 17 A. You read it correctly. But it's also, in 18 my mind, it's unclear, you know -- you know, again, 19 like, there's no detail as far as, like, the methods and 20 such. So if they're doing this as powders and then 21 they're reanalyzing, so they're repacking the powder at 22 a sample volume can be several cubic centimeters. So 23 it's not necessarily surprising that we would have a 24 positive result and then, if you repack it, you might 25 get a negative result. And their interpretation is</p>	<p>1 MS. SCOTT: Objection. 2 A. Well, I would say it's probable -- 3 BY MR. FROST: 4 Q. And what's that based on? 5 A. -- or possible. 6 Q. What's your basis? 7 A. The first finding. 8 Q. And the fact that it was negated and 9 specifically retracted by the person who does the 10 testing has absolutely no sway in your mind as to 11 whether or not? You're just now basing your opinion on 12 speculation? 13 MS. SCOTT: Objection. 14 BY MR. FROST: 15 Q. Don't you think the guy who did the test 16 is in a better position than you are today, 40, 50 years 17 later, to say what was in that particular sample that he 18 tested? 19 MS. O'DELL: Objection. 20 A. I've stated my opinion. 21 BY MR. FROST: 22 Q. Okay. Interesting one. Let's turn to 23 1972. It's page 16. 24 A. There's many from '72 here. Which one? 25 Q. It's the very -- it's 8/3/1972.</p>

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<p>1 A. "8/3/1972, J&J-28, NYU, Shower to Shower 2 ... 5 percent chrysotile." 3 Q. Turn to Tab 8. I'm sorry. Tab 10. 4 A. Tab 10. 5 Q. Do you agree this is a corresponding 6 document to that entry? 7 A. J&J-28. Yes. 8 Q. Okay. Real quick, before I get there, 9 turning back to Tab 9, you were never provided with this 10 document, right? 11 MS. SCOTT: Objection. 12 A. Tab 9. I think I was. 13 BY MR. FROST: 14 Q. And then why didn't you consider this 15 document in creating your chart? 16 MS. SCOTT: Objection. 17 A. I potentially missed it in the 18 compilation. 19 BY MR. FROST: 20 Q. And you also didn't include it under 21 materials considered? 22 A. I missed it. 23 Q. Okay. So back to Tab 10. So we agree 24 this is the source of the entry on page 16 of your 25 report, correct? The Shower to Shower sample 84.</p>	<p>1 MS. O'DELL: Give us just a minute. 2 A. Here's one by Doctor -- I'm sorry. I'm 3 getting Dr. Lewin-- okay. D. You said D-1? 4 MS. O'DELL: Is it DX? 5 MR. FROST: I have it as D. It's 6 possible it's DX. 7 A. So let's see what the date is. We have a 8 date. We're looking for January 7th, '76. January 7th, 9 '76. I think there's only -- I have one. I have only 10 one. 11 BY MR. FROST: 12 Q. Sir, we're trying to pull up the 13 documents, but this relates -- and I'll get back -- but 14 this relates to your testing of 8/3/72 by Dr. Lewin. 15 The Shower to Shower sample 84, you note on the 8/3/72. 16 If you look back at Tab 10, that's the corresponding 17 document for that. It's on the one, two, three, four, 18 five, sixth page. 19 MS. SCOTT: Is subsection B on the 20 tabulation of Dr. Lewin's original findings 21 smudged? 22 MR. FROST: Yeah, it's smudged, too. 23 MS. SCOTT: Okay. 24 MR. FROST: Yeah. Mine looks the same. 25 MS. SCOTT: Got it. And that's the</p>
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<p>1 A. Yeah. J&J-28? 2 Q. Yes. 3 A. Yes. 4 Q. Okay. And this was testing that was done 5 by Dr. Lewin? 6 A. Yes. 7 Q. Are you aware that Dr. Lewin retested 8 this sample and was unable to replicate his results? 9 A. No. 10 Q. Okay. Turn to Tab 11. If you look at 11 page 4, it's the testing of Number 29. I think it's 12 four -- three down. 13 A. It is one, two, three, four. And I'm 14 sorry. This is -- 15 Q. Yes. That's the chart. 16 A. Where? I don't see a number on this. 17 Q. Yeah. It appears to have gotten cut off, 18 so I don't know what the number of this document is. We 19 can sort that out at the back end. 20 A. Where is it at on the chart? 21 Q. It's D-7113. As I said, it got cut off. 22 MS. O'DELL: Yeah. Was it marked in a 23 deposition? 24 MR. FROST: I believe it is. It's marked 25 somewhere, but I have it in my notes as D-7113.</p>	<p>1 original? 2 MR. FROST: Yes. My understanding is 3 that's the original. 4 BY MR. FROST: 5 Q. Okay. So you see we're talking about 6 Sample 84 on Tab 10? 7 A. Right. So I'm at Tab 10. Tab 10. 8 Q. One, two, three, four -- it's the fifth 9 page. 10 A. One, two, three, four, five. 11 Q. Do you see a Product 84? 12 A. Product 84? Yes. 13 Q. And if you follow across, there's -- 14 A. 5 percent chrysotile. 15 Q. -- 5 percent chrysotile. Okay. So if 16 you turn to the document at Tab 11. 17 MS. O'DELL: I'm not able to find that 18 DX. 19 MR. FROST: Okay. Well, I'll provide it 20 to you after the deposition. We'll figure it 21 out. 22 BY MR. FROST: 23 Q. So if you look at this, this document, 24 you go to the fourth page. Sorry. One, two, three, 25 fourth page.</p>

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<p style="text-align: right;">Page 258</p> <p>1 A Okay. One, two, three, four.</p> <p>2 Q. Do you see here under Sample 84 with the</p> <p>3 retest that there's a no detect and there's no finding</p> <p>4 of chrysotile?</p> <p>5 MS. SCOTT: Objection.</p> <p>6 A. In the -- oh, there's a question mark for</p> <p>7 chrysotile, right?</p> <p>8 BY MR. FROST:</p> <p>9 Q. Yeah. It certainly doesn't find that</p> <p>10 there's chrysotile in the retest, correct?</p> <p>11 MS. SCOTT: Objection.</p> <p>12 A. It doesn't say "no detect," also.</p> <p>13 BY MR. FROST:</p> <p>14 Q. Again, without speculating, can you tell</p> <p>15 me whether or not that that means there's chrysotile in</p> <p>16 that product?</p> <p>17 A. No. But it means there's some question.</p> <p>18 Yeah, I don't know why they would use question marks.</p> <p>19 If it was no detect, I would expect it to be an ND.</p> <p>20 Q. But, again, you can't tell me one way or</p> <p>21 the other without speculating that there's chrysotile in</p> <p>22 that product, correct?</p> <p>23 MS. O'DELL: Object to the form.</p> <p>24 A. So with all these, you know, re-analyses,</p> <p>25 you know, essentially, one aspect of variability is that</p>	<p style="text-align: right;">Page 260</p> <p>1 Powder, 3 percent chrysotile.</p> <p>2 Q. You're looking at page 4 of 7?</p> <p>3 A. 4 of 7.</p> <p>4 Q. Samples 183 and 184?</p> <p>5 A. Yes.</p> <p>6 Q. If you look back at Tab 11. If you look</p> <p>7 at Samples 133 and 134 here. Again, on the retest, this</p> <p>8 time there's no question mark. It says nondetect for</p> <p>9 chrysotile, tremolite. Do you agree?</p> <p>10 A. 133 and 134, ND. Yes, ND is listed.</p> <p>11 Q. And if you look back at your chart on</p> <p>12 16 -- strike that.</p> <p>13 So, again, looking at this, you can't</p> <p>14 tell me whether or not there's actually asbestos that</p> <p>15 made it into the sample that's listed as 9/26/72 in your</p> <p>16 chart, correct, without speculating?</p> <p>17 A. Correct. It was detected once in a</p> <p>18 sample, and it was not detected again in what is</p> <p>19 supposedly the same sample. So I'm unclear. Is it the</p> <p>20 exact -- is it the same exact sample or same lot?</p> <p>21 Q. It's the same sample, sir. It was</p> <p>22 retesting of the same sample.</p> <p>23 A. Resting.</p> <p>24 MS. O'DELL: Object to the form.</p> <p>25 A. Is the exact --</p>
<p style="text-align: right;">Page 259</p> <p>1 perhaps the samples were either ground more or not</p> <p>2 prepared, you know, in the same way.</p> <p>3 BY MR. FROST:</p> <p>4 Q. Let's stop you here. You're speculating</p> <p>5 about all of this, correct? Based on these documents,</p> <p>6 can you tell me one way or the other that there was any</p> <p>7 problems with the retest or that they've actually found</p> <p>8 chrysotile in any of these samples? I don't want you to</p> <p>9 speculate.</p> <p>10 MS. SCOTT: Object to the form.</p> <p>11 A. The -- this has a question mark listed</p> <p>12 for chrysotile.</p> <p>13 BY MR. FROST:</p> <p>14 Q. And based on that, you can't tell me one</p> <p>15 way or the other whether there was chrysotile in the</p> <p>16 final sample that was tested, according to this</p> <p>17 document, correct?</p> <p>18 A. Correct. According to that document.</p> <p>19 Q. Okay. Go to your chart. Still on page</p> <p>20 16, I believe. It's 9/26/72.</p> <p>21 A. 9/26/72.</p> <p>22 Q. If you turn to Tab 12. Do you agree that</p> <p>23 that's the corresponding document, J&J-31?</p> <p>24 A. JNJ-31. I believe so, yes. Johnson's</p> <p>25 Baby Powder, 2 percent chrysotile; Johnson's Baby</p>	<p style="text-align: right;">Page 261</p> <p>1 MS. O'DELL: Excuse me. Object to the</p> <p>2 form.</p> <p>3 BY MR. FROST:</p> <p>4 Q. You can read the document yourself, sir.</p> <p>5 All right. So I think we've gone</p> <p>6 through, like, six of these, correct? And we've come up</p> <p>7 with six of them either are samples that have absolutely</p> <p>8 nothing to do with Johnson's Baby Powder or Shower to</p> <p>9 Shower or any other cosmetic talcum problem. Do you</p> <p>10 agree? Talcum powder product.</p> <p>11 MS. O'DELL: Objection.</p> <p>12 BY MR. FROST:</p> <p>13 Q. Do you agree?</p> <p>14 A. We've gone through six examples as</p> <p>15 you've -- yeah.</p> <p>16 Q. And others we've come up with, we</p> <p>17 basically determined without speculating you can't say</p> <p>18 one way or the other that there is asbestos in that</p> <p>19 product that made it onto the market, correct?</p> <p>20 MS. SCOTT: Object to the form.</p> <p>21 A. Based on those documents, yes.</p> <p>22 BY MR. FROST:</p> <p>23 Q. So I think it would take us days to go</p> <p>24 through all of these, but can you definitively sit here</p> <p>25 now and tell me that every single hit or every single</p>

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<p>1 reference you have on this list showing asbestos and 2 talcum powder is actually talcum powder that was, one, 3 either use or ended up in an bottle of Johnson's Baby 4 Powder or Shower to Shower or other talcum powder 5 products or, two, that you can say without speculating 6 contains asbestos? 7 MS. O'DELL: Objection. 8 A. To the best of my knowledge, I stand by 9 the report. 10 BY MR. FROST: 11 Q. But sitting here today, you can't tell me 12 one way or the other that absolutely every -- well, we 13 know not every single entry is correct? 14 MS. O'DELL: Objection. 15 A. Yeah. So there -- there are some 16 misidentifications or later corrections, later 17 corrections that I was unaware of, but it's also 18 concerning that you can -- it's not exactly -- you know, 19 so what is a sample? It's not exactly clear if the 20 sample is like a kilogram sample, so you could have 21 portions in that sample that have asbestos that you 22 cannot detect, and then you can have regions of the 23 sample that have a lot. So that, that's my opinion. 24 Q. So what you're telling me is you can't 25 actually speculate as to any of the testing results in</p>	<p>1 they provided to you? 2 MS. SCOTT: Objection. 3 A. No. But I -- well, I remember there's a 4 deposition by Blount who indicated, I think, on page 10 5 that work from 1991 was Johnson & Johnson talcum powder, 6 if I remember correctly. I've seen that somewhere. 7 BY MR. FROST: 8 Q. Okay. So Blount, Longo. And, again, 9 Blount was provided to you by plaintiffs' counsel, 10 correct? 11 A. Yes. 12 Q. Now, you've done no additional testing 13 yourself of talcum powder? I think you said that 14 before. 15 A. Correct. Yeah. That was not requested 16 of me. 17 Q. And have you done any testing or cusing 18 of the testing done by Dr. Longo? 19 MS. SCOTT: Objection. Asked and 20 answered. 21 A. No. I was not asked to retest on any of 22 his samples or anything like that. 23 BY MR. FROST: 24 Q. So you're merely relying on the results 25 of his testing for purposes of your opinions here,</p>
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<p>1 here because of the various sample sizes retesting, and 2 again, not everything we found is a retest, right? Some 3 aren't even products of cosmetic talc, correct? 4 MS. O'DELL: Object to the form. 5 MS. SCOTT: Objection. 6 A. I don't remember. 7 BY MR. FROST: 8 Q. You don't remember that we found talcum 9 powder that came from a mine in San Andreas, California? 10 A. I'm sorry. Yeah, that's correct. 11 Q. Okay. So it's not just retesting that 12 came back. I've also identified some product that has 13 nothing to do with cosmetic talcum powder, correct? 14 MS. SCOTT: Objection. 15 A. Correct. 16 BY MR. FROST: 17 Q. Okay. Now, you also reference in your 18 report Dr. Longo's reports; is that correct? 19 A. Yes. 20 Q. And I take it you were provided those 21 reports by plaintiffs' counsel? 22 A. Yes. 23 Q. Did you ever ask plaintiffs' counsel if 24 anybody else has done testing of Johnson & Johnson 25 talcum powder other than Dr. Longo and the records that</p>	<p>1 correct? 2 A. Yes. 3 Q. You have no opinions about his sample 4 preparation, his underlying testing methods, anything of 5 that nature? 6 A. I'm fine with what he's done. 7 Q. Okay. But you're not rendering any 8 opinions that it's correct or incorrect or the 9 methodology about it? You're not going to sit here 10 today and walk me through the methodology that Longo 11 used to give me opinions that that's the proper way or 12 not the proper way? 13 MS. SCOTT: Objection. 14 A. I think what he did was fine for the 15 purpose of the report. 16 BY MR. FROST: 17 Q. You have no problems with any of the 18 methodology he employed in his testing? 19 MS. O'DELL: Objection. Asked and 20 answered. 21 A. No. I'm fine with what he's done in the 22 report. 23 BY MR. FROST: 24 Q. This is despite the fact that you've done 25 nothing to verify the results of his report?</p>

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<p>1 MS. SCOTT: Objection.</p> <p>2 A. You know, I looked at a lot of TEM data.</p> <p>3 You know, just looking at the quality of the data,</p> <p>4 electron diffraction is, requires a certain level of</p> <p>5 skill, and he produced several, you know, really good</p> <p>6 nets, so he was obviously able to get good orientations</p> <p>7 of crystals. So, you know, he didn't have anything that</p> <p>8 was extremely off axis or anything like that. So at</p> <p>9 that level, I mean, I am fine with his data.</p> <p>10 BY MR. FROST:</p> <p>11 Q. You didn't go through and actually run</p> <p>12 any calculations to determine whether or not his</p> <p>13 accessions were correct or whether or not any of his</p> <p>14 underlying calculations or determinations are correct?</p> <p>15 MS. SCOTT: Objection. Asked and</p> <p>16 answered.</p> <p>17 A. I did not index things, but the</p> <p>18 diffraction patterns looked suitable and consistent as</p> <p>19 to the EDS, suitable and consistent with the materials</p> <p>20 that he identified.</p> <p>21 BY MR. FROST:</p> <p>22 Q. And is suitable and consistent the</p> <p>23 scientific requirement for testing?</p> <p>24 MS. SCOTT: Objection.</p> <p>25 A. So with TEM work, essentially, one should</p>	<p>1 found asbestos in every sample he tested?</p> <p>2 A. I would not be comfortable saying that.</p> <p>3 I don't know.</p> <p>4 Q. Okay.</p> <p>5 A. I know he found asbestos in many samples.</p> <p>6 Q. Okay. Turning to -- where I did put your</p> <p>7 report?</p> <p>8 THE WITNESS: Can we take a little break?</p> <p>9 MR. FROST: Sure.</p> <p>10 VIDEOGRAPHER: We're now going off</p> <p>11 record. The time is 5:47.</p> <p>12 (A recess was taken from 5:47 to 6:00.)</p> <p>13 VIDEOGRAPHER: We are back on record, and</p> <p>14 the time is 6:00.</p> <p>15 BY MR. FROST:</p> <p>16 Q. We're going to change gears a little bit</p> <p>17 and talk about fibrous talc. Of course, I'm not finding</p> <p>18 it. That's all right. It doesn't matter.</p> <p>19 So, in general, you're relying on the</p> <p>20 IARC statement from 2012, correct, that fibrous talc is</p> <p>21 carcinogenic?</p> <p>22 A. I'm just trying to find it.</p> <p>23 BY MR. FROST:</p> <p>24 Q. If you find it, tell me the page. Okay.</p> <p>25 Page 23 is where it starts.</p>
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<p>1 have an image, an EDS pattern and a diffraction pattern.</p> <p>2 So I find what he has done is in agreement with what I</p> <p>3 would do and what others have done.</p> <p>4 BY MR. FROST:</p> <p>5 Q. This is despite the fact that you didn't</p> <p>6 do any retesting of the work calculations. You didn't</p> <p>7 do any cusing of it. You're just taking it a face value</p> <p>8 based on your review?</p> <p>9 MS. SCOTT: Objection.</p> <p>10 A. I was not tasked with retesting samples.</p> <p>11 BY MR. FROST:</p> <p>12 Q. You agree with me that there are samples</p> <p>13 where Dr. Longo detected no asbestos, correct?</p> <p>14 A. I'm not sure. There may have been some,</p> <p>15 but I don't remember the exact details.</p> <p>16 Q. So you're relying on Dr. Longo's report</p> <p>17 and testing as a basis for your opinions here, but you</p> <p>18 can't even tell me whether or not what percentage or if</p> <p>19 he finds no asbestos in some of the bottles he tested?</p> <p>20 MS. SCOTT: Objection.</p> <p>21 A. There were, you know, hundreds and</p> <p>22 hundreds of images diffraction patterns in EDS, so I</p> <p>23 don't remember specifics.</p> <p>24 BY MR. FROST:</p> <p>25 Q. So you can't tell me whether or not he</p>	<p>1 A. Twenty-three.</p> <p>2 Q. In general, I think a couple different</p> <p>3 places in your report, you note that, according to IARC,</p> <p>4 it's actually -- I see it on page 3. Yeah, that rely on</p> <p>5 IARC 2012 to state that fibrous talc can be a human</p> <p>6 carcinogen?</p> <p>7 A. I'm sorry. You said page 3?</p> <p>8 Q. Yes.</p> <p>9 A. Page 3.</p> <p>10 MS. SCOTT: I'll just object.</p> <p>11 A. "Talc can occur in a fibrous habit"?</p> <p>12 Q. Yep.</p> <p>13 A. "These fibers can be inhaled into the</p> <p>14 lower lungs based on their length and diameter,</p> <p>15 producing effects linked to significant health risks in</p> <p>16 humans. IARC 2012."</p> <p>17 BY MR. FROST:</p> <p>18 Q. Okay. Would you agree with me that</p> <p>19 you're not an expert in reading the literature of what</p> <p>20 causes cancer?</p> <p>21 MS. SCOTT: Objection.</p> <p>22 A. I am not an oncologist. I am not a</p> <p>23 medical expert.</p> <p>24 BY MR. FROST:</p> <p>25 Q. Do you agree with me that an IARC</p>

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<p>1 monograph does not represent independent lab work but, 2 instead, it's a summary of work that's already been done 3 by others? 4 MS. SCOTT: Objection. 5 A. And that's normal. There are many 6 monographs. I mean, we have, you know, the CRC 7 chemistry book. 8 BY MR. FROST: 9 Q. That's what I'm saying. 10 A. It is a cumulative document, as I 11 understand it, based on peer-review literature, and it's 12 also an international document, so it's global 13 peer-review literature, as I understand it. 14 Q. Do you agree with me that if there are -- 15 IARC does not draw conclusions on its own, so if there's 16 not peer-reviewed literature that says one way or the 17 other, IARC isn't going to jump out and say this is or 18 this isn't, correct? IARC relies on the work of others 19 in order to reach its conclusions? 20 MS. O'DELL: Object to form. 21 A. I think it's speculation because I'm not 22 an expert in health and medical things. 23 BY MR. FROST: 24 Q. Okay. Are you aware whether or not there 25 are any peer-reviewed studies that actually link</p>	<p>1 BY MR. FROST: 2 Q. If you want me to explain it -- 3 A. I don't -- I don't remember. 4 Q. And that, specifically, the theory is 5 that -- you know, the explanation is that if you look at 6 talc edge on, it can appear in a 2-D image as fibrous. 7 Would you agree with that? 8 MS. SCOTT: Objection. 9 A. Can I make a statement? 10 BY MR. FROST: 11 Q. Sure. 12 A. So the miopyroboles are this mineral 13 group that actually were discovered in the ultramafic, 14 these talc-rich zones in Vermont. So Dave Devlin, I 15 worked with Thompson at Harvard, and basically, what 16 they showed is that you can have these structural 17 intermediates where, essentially, you can have a region 18 of a crystal. 19 Q. Okay. I am going to stop you because we 20 are talking about something completely different. My 21 question was -- 22 A. I was explaining how one might get 23 fibrous talc. 24 Q. No, no. I'm talking about -- that's why 25 I stopped you, because that's not what we're talking</p>
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<p>1 exposure to talc to ovarian cancer? 2 MS. SCOTT: Objection. 3 MS. O'DELL: Object to form. 4 A. I'm sorry. Any studies or any 5 information? 6 BY MR. FROST: 7 Q. I said any peer-reviewed studies linking 8 exposure to talc to ovarian cancer. 9 A. I'm not a medical expert. 10 Q. Again, can you tell me whether or not 11 IARC specifically links exposure to talc to ovarian 12 cancer? 13 MS. SCOTT: Objection. Asked and 14 answered. 15 MS. O'DELL: Objection. 16 A. I'm not a medical expert. 17 BY MR. FROST: 18 Q. Have you ever done any work identifying 19 talc as either platy or fibrous? 20 A. No. I have no peer-reviewed articles. 21 Q. Are you aware if you ever heard of the 22 common misreporting of platy talc as fibrous? 23 MS. SCOTT: Objection. 24 MS. O'DELL: Objection. 25</p>	<p>1 about. 2 So do you agree that if you're looking at 3 a plate of talc on edge, it can appear as a fiber in a 4 2-D SEM or TEM image? And have you read any literature 5 about the problems with misidentifying talc? 6 MS. O'DELL: Objection. 7 MS. SCOTT: Objection. 8 A. It can look -- so a fibrous -- a fiber 9 can look like a two-dimensional plate or a 10 two-dimensional plate can look like a fiber. 11 BY MR. FROST: 12 Q. So the problem is when you're looking -- 13 because, usually, a platy talc, you know, if it's 14 sitting oriented this way, you can see the large 15 platiness of it, but if it's oriented that you're 16 looking at the flat plane, have you ever read anything 17 that talks about the fact that you can misidentify platy 18 talc as fiber based on the orientation of the image? 19 MS. SCOTT: Objection. 20 A. I don't remember. 21 MR. FROST: Can we get IARC 2010? I 22 forget what that was marked as. It's the big 23 orange one, I believe. Yeah, there it is. 24 MS. O'DELL: Five. 25 MR. FROST: It looks like that. It's</p>

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<p>1 five.</p> <p>2 BY MR. FROST:</p> <p>3 Q. I'll skip this. You said you haven't</p> <p>4 read anything. You don't know about that, so it's not</p> <p>5 something that comes up in your work?</p> <p>6 A. I don't remember.</p> <p>7 Q. That's fine. I'll move on for sake of</p> <p>8 time. All right.</p> <p>9 Now, you've also noted in your report</p> <p>10 various opinions about findings of nickel, chromium and</p> <p>11 cobalt, correct?</p> <p>12 A. Yes.</p> <p>13 Q. And you're not qualified to opine as to</p> <p>14 whether or not a particular level of nickel is</p> <p>15 sufficient to cause human disease, correct?</p> <p>16 MS. SCOTT: Objection.</p> <p>17 A. I am not a toxicologist.</p> <p>18 BY MR. FROST:</p> <p>19 Q. You're also not qualified to opine what,</p> <p>20 if any, disease may be associated with nickel</p> <p>21 contaminated or with nickel exposure, correct?</p> <p>22 MS. SCOTT: Objection.</p> <p>23 A. I'm not a toxicologist or oncologist.</p> <p>24 BY MR. FROST:</p> <p>25 Q. I'm looking at your report, starting on</p>	<p>1 finished talcum powder, correct?</p> <p>2 MS. SCOTT: Objection.</p> <p>3 MS. O'DELL: Objection.</p> <p>4 A. I'm sorry. Repeat the question.</p> <p>5 BY MR. FROST:</p> <p>6 Q. Sure. You can't tell me without</p> <p>7 speculating that levels of -- we're looking at nickel,</p> <p>8 for example, here, found in ore samples are the same</p> <p>9 levels that would be located in finished talcum powder,</p> <p>10 correct?</p> <p>11 MS. SCOTT: Objection.</p> <p>12 A. Correct. The levels of metals may be the</p> <p>13 same, may be less or may be more depending upon the</p> <p>14 process.</p> <p>15 BY MR. FROST:</p> <p>16 Q. And things like beneficiation, blending,</p> <p>17 things of this nature would ultimately affect what ends</p> <p>18 up in the final product, right?</p> <p>19 A. If it's executed correctly, but I think</p> <p>20 it's also reasonable to say that some -- it is</p> <p>21 scientifically likely -- it's my opinion that some of</p> <p>22 this would, from the ore samples, would make it into</p> <p>23 product if it is used for that purpose.</p> <p>24 Q. But you can't tell me, of these ore</p> <p>25 samples, what sample may or may not have made --</p>
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<p>1 page 34.</p> <p>2 A. I'm right there.</p> <p>3 Q. Some of these tests, you'll agree with</p> <p>4 me, you know, not that they're from ore. Several of</p> <p>5 them actually note that they're from ore grade 66.</p> <p>6 Windsor 66, you agree, is an ore, correct?</p> <p>7 MS. O'DELL: Object to the form.</p> <p>8 A. I'm sorry?</p> <p>9 BY MR. FROST:</p> <p>10 Q. You'd agree with me, looking at these,</p> <p>11 that the marks that say "ore in concentrate, grade 66,</p> <p>12 Windsor 66," et cetera, these are all ore samples,</p> <p>13 correct?</p> <p>14 MS. SCOTT: Objection.</p> <p>15 A. I think so. I'd like to look at the</p> <p>16 document to be sure.</p> <p>17 BY MR. FROST:</p> <p>18 Q. I mean, you can go on them, such as the</p> <p>19 example of Imerys 045182. It says three ore samples?</p> <p>20 A. Yeah. So that's what it's listed as,</p> <p>21 yes.</p> <p>22 Q. So you'd agree with me without</p> <p>23 speculating, you can't say one way or the other that</p> <p>24 levels, as detected in the ore samples, are actually the</p> <p>25 levels that may have ever made it into a bottle of</p>	<p>1 A. I can't tell you where, what bottle that</p> <p>2 might have ended up in, yes.</p> <p>3 Q. Or if it even could have ended up in the</p> <p>4 bottle, correct?</p> <p>5 MS. SCOTT: Objection.</p> <p>6 BY MR. FROST:</p> <p>7 Q. At that --</p> <p>8 A. Specifically, no.</p> <p>9 Q. Okay.</p> <p>10 A. If you process it, you may modify it one</p> <p>11 way or the other.</p> <p>12 Q. The same thing would also be true with</p> <p>13 respect to the chromium, cobalt, and I think this is the</p> <p>14 only other ones, right, chromium, cobalt that are listed</p> <p>15 in the charts? Yes.</p> <p>16 MS. SCOTT: Objection.</p> <p>17 BY MR. FROST:</p> <p>18 Q. The same would be true with chromium and</p> <p>19 cobalt, right?</p> <p>20 A. Chromium, cobalt, nickel. Chromium</p> <p>21 cobalt, nickel -- I'm just checking and double checking.</p> <p>22 Chromium, cobalt, and then it's not in chart form, but I</p> <p>23 do talk about arsenic on page 33.</p> <p>24 Q. And it would be the same for the</p> <p>25 chromium, cobalt, nickel and arsenic based on ore sample</p>

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<p>1 testing? You couldn't say one way or the other what</p> <p>2 level ultimately made it into, if at all, talcum powder,</p> <p>3 finished talcum powder, correct?</p> <p>4 MS. SCOTT: Objection.</p> <p>5 A. Yes.</p> <p>6 BY MR. FROST:</p> <p>7 Q. With respect to chromium, which is page</p> <p>8 36 of your report, sir?</p> <p>9 A. Uh-huh.</p> <p>10 Q. You know that chromium can occur in two</p> <p>11 different forms, Chromium III and Chromium VI?</p> <p>12 A. It's a slight typo. What I mean to say</p> <p>13 there is chromium can occur in two common forms and</p> <p>14 minerals, Chromium III and Chromium IV. So chromium can</p> <p>15 actually have several different valent states to it --</p> <p>16 Q. And it's Chromium VI --</p> <p>17 A. -- including the zero valent metal, which</p> <p>18 we don't really see in nature.</p> <p>19 Q. And it's chromium 6, correct, that is the</p> <p>20 known carcinogen?</p> <p>21 A. Yeah. That is one of high concern, as I</p> <p>22 understand it.</p> <p>23 Q. Are you generally aware that Chromium III</p> <p>24 is actually an essential element in the human body?</p> <p>25 A. I'm a diabetic. Yes.</p>	<p>1 Q. It you turn to, I believe, Exhibit 2,</p> <p>2 your supplemental report.</p> <p>3 A. Okay.</p> <p>4 Q. Okay. The second page.</p> <p>5 A. Okay.</p> <p>6 Q. Under sampling and techniques, do you see</p> <p>7 it's one, two, three, four down?</p> <p>8 A. Under "Sampling and Testing"?</p> <p>9 Q. Under "Sampling and Testing Results,"</p> <p>10 yes. You know that it failed to provide data</p> <p>11 supporting -- no. I'm in the wrong place.</p> <p>12 A. I'm sorry. Where were you?</p> <p>13 Q. Sorry. I was in the wrong place. Bear</p> <p>14 with me a second here. Okay. It's the one, two, third</p> <p>15 paragraph down. It starts with "Another issue."</p> <p>16 A. Yeah.</p> <p>17 Q. So "Another issue was the vague</p> <p>18 description of the preparation technique. The method</p> <p>19 fails to identify whether the material was ground,</p> <p>20 crushed or made into a powder by another method." Do</p> <p>21 you see that there?</p> <p>22 A. Yes.</p> <p>23 Q. If you look up to the testing, it says,</p> <p>24 "XRD methodology states." Do you see where I am there?</p> <p>25 A. Yes.</p>
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<p>1 Q. Okay. And are you also aware that</p> <p>2 chromium 3 is commonly found in rocks and minerals?</p> <p>3 A. Yes.</p> <p>4 Q. And, again, in looking at the chart, you</p> <p>5 don't list here whether or not it is Chromium III,</p> <p>6 Chromium VI or some other variant of the mineral -- or</p> <p>7 the metal, correct?</p> <p>8 A. Correct. But I think it's reasonable</p> <p>9 that -- yes. There's no specific determination of</p> <p>10 valent state, which would have been a nice step if you</p> <p>11 could definitively show that there is no chromium or</p> <p>12 active valent chromium that would have been a good</p> <p>13 thing. But, yes, there's no specific EELS, electron</p> <p>14 energy loss spectroscopy, or what comes through</p> <p>15 techniques to determine that.</p> <p>16 Q. And with respect to the arsenic, the</p> <p>17 cobalt and the chromium, just like the nickel, you can't</p> <p>18 tell me what level of exposure is required to cause</p> <p>19 disease of those heavy metals, correct?</p> <p>20 A. I am not a medical or oncologist, sir,</p> <p>21 yes.</p> <p>22 Q. And it's the same thing. You couldn't</p> <p>23 tell me what diseases they're known to cause if you have</p> <p>24 exposure, correct?</p> <p>25 A. Correct.</p>	<p>1 Q. It's the part that's indented.</p> <p>2 Underneath, it says, "Monthly talc composite, February</p> <p>3 1990."</p> <p>4 A. Yeah.</p> <p>5 Q. Do you agree with me that the monthly</p> <p>6 talc composite is a composite of the ground finished</p> <p>7 talc that's being tested?</p> <p>8 MS. SCOTT: Objection.</p> <p>9 A. I'm unsure. I'm unsure. The -- you --</p> <p>10 one would essentially prepare the -- I'm sorry. Go</p> <p>11 ahead.</p> <p>12 BY MR. FROST:</p> <p>13 Q. Yes.</p> <p>14 A. I'm unsure.</p> <p>15 Q. You can't tell me whether or not this was</p> <p>16 the composite sample of the already ground and prepared</p> <p>17 talc?</p> <p>18 A. I don't -- I don't remember specifically.</p> <p>19 Q. And if the talc was already ground as a</p> <p>20 finished product, there wouldn't be further grinding of</p> <p>21 it. Do you agree with that?</p> <p>22 MS. SCOTT: Objection.</p> <p>23 A. So as I understand, the final talc</p> <p>24 particle size is approximately 15, 25 microns or so, so</p> <p>25 that's essentially fine salt size. So, typically, in</p>

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<p style="text-align: right;">Page 282</p> <p>1 power diffraction, you would want to reduce that 2 particle size further. 3 BY MR. FROST: 4 Q. Did you see anywhere in reviewing this 5 testing that they state that they reduce the particle 6 size further? 7 MS. O'DELL: If you need to review the 8 document, Doctor, we can pull it. 9 A. Yeah. Why don't we pull it up? 10 BY MR. FROST: 11 Q. Sure. I don't have it. That's fine. We 12 can move on. I don't want to waste my time. 13 MS. O'DELL: To ask him questions, 14 specific questions about the document not having 15 this. 16 MR. FROST: I'm just asking -- I'm just 17 asking if he knows and what he remembers in 18 drafting his report. 19 All right, sir. I think that's all the 20 questions I have for now. I reserve the right 21 to look at my notes and come back, but I'm going 22 to yield my time to some of the other 23 defendants. We can go off the record. 24 VIDEOGRAPHER: We're now going off 25 record. The time is 6:19.</p>	<p style="text-align: right;">Page 284</p> <p>1 A. Yes. 2 Q. And you've published a hundred and 3 something; is that right? 4 A. Over 40 peer-review papers. I have over 5 a hundred presentations at meetings and a couple 6 patents, yes. 7 Q. In your peer-review papers, when you're 8 citing authorities in your peer-review papers, you tend 9 to or customarily cite peer-reviewed papers, don't you? 10 A. Generally, yes. 11 Q. Because you know that they have the 12 likelihood to be more accurate and have been, obviously, 13 reviewed by peers, correct? 14 MS. O'DELL: Object to form. 15 A. Correct, yes. 16 BY MR. FERGUSON: 17 Q. Now, in your report that you did in this 18 case, and I know it's been marked as an exhibit. I 19 forget which number. In your report in this case, you 20 have, among other authorities, cited Dr. Longo and 21 Dr. Rigler's report, correct? 22 A. I've cited expert witness reports, yes. 23 Q. And you understand that Dr. Longo and 24 Rigler's report, that's not peer reviewed, correct? You 25 understand that?</p>
<p style="text-align: right;">Page 283</p> <p>1 (A recess was taken from 6:19 to 6:33.) 2 VIDEOGRAPHER: We are now back on record, 3 and the time is 6:33. 4 CROSS-EXAMINATION 5 BY MR. FERGUSON: 6 Q. Good evening, Dr. Krekeler. How are you? 7 A. Good. 8 Q. Okay. We met briefly before. My name is 9 Ken Ferguson, and I represent Imerys. Do you understand 10 that? 11 A. Yes. 12 Q. Okay. And I've got, along with Mr. Cary, 13 who's down, three people down from me. 14 A. Okay. 15 Q. I've got some questions for you. I'm not 16 going to spend a lot of time, because there's not a lot 17 of time left, so I may skip around a little, just 18 depending on which questions I feel like I need to get 19 asked before I run out of time. So I'm not trying to 20 confuse you by that, but if I do, then you let me know, 21 and I'll restate the question, okay? 22 A. Okay. 23 Q. Okay. Fair enough. 24 So in your career as an academic, you've 25 written scientific papers before, correct?</p>	<p style="text-align: right;">Page 285</p> <p>1 A. Yes, I do. 2 Q. So while your custom is to cite 3 peer-reviewed articles in your scientific papers that 4 you're writing, you've varied from that in doing your 5 report here in this matter, correct? 6 MS. O'DELL: Object to the form. 7 A. Yes. So I have not in my previous work 8 cited an expert witness report. 9 BY MR. FERGUSON: 10 Q. And you understand that Dr. Longo and his 11 colleague, Dr. Rigler, and I think they wrote these 12 reports together, that they are being paid as experts by 13 counsel for plaintiffs just as you are, correct? 14 MS. SCOTT: Objection. 15 A. I believe that is the case, yes. 16 BY MR. FERGUSON: 17 Q. I want to talk to you a little bit about 18 a book that I see you've got your copy out. I've got my 19 copy out, and we have some copies we've made that I'm 20 going to mark as Exhibit 23, I believe. 21 (Exhibit 23 was marked for 22 identification.) 23 BY MR. FERGUSON: 24 Q. Now what I've marked, Dr. Krekeler, are 25 some pages from a book called "An Introduction to the</p>

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<p>1 Rock-Forming Minerals" by Deer, Howie and Zussman, 2 correct? 3 A. Is this the same edition? 4 Q. I believe -- I believe it's the third 5 edition. 6 A. Oh, I'm sorry. 7 Q. And yours is? 8 A. Third. Yeah, we're good. 9 Q. This is a book that is often relied upon 10 by mineralogists, correct, material scientists? 11 A. This is a book that is used as a textbook 12 for mineralogy courses, yes. 13 Q. So let's go back to your report, and if 14 you would, just keep the Deer, Howie and Zussman by your 15 side. Go to your report at page 5. Are you with me? 16 A. Page 5. 17 Q. And in the first paragraph on page 5 of 18 your report, there's a sentence in the middle that says, 19 "As a result, natural talc formation is commonly 20 accompanied by veins of other minerals, including 21 asbestiform minerals like tremolite and serpentine," 22 correct? 23 A. Yes. 24 Q. And you cite for that Deer, Howie & 25 Zussman 2013, correct?</p>	<p>1 (Exhibit 24 was marked for 2 identification.) 3 BY MR. FERGUSON: 4 Q. And this is a paper by a Harold R. 5 Newman, correct? 6 A. That's what it says. 7 Q. And it says, "The Mineral Industry of 8 Italy," correct? 9 A. Yes. What journal did this come from? 10 Is this peer review? 11 Q. I don't know. I believe it is, but I 12 don't know the answer, so I'm not going to answer it. 13 A. You believe or it is? 14 Q. I get to ask the questions. 15 A. All right. 16 Q. We have Harold Newman's paper here, okay? 17 A. Okay. 18 Q. From The Mineral Institute of Italy, 19 right? 20 A. Mineral Industry of Italy, one. 21 Q. So look at page -- 22 A. I'm sorry? 23 Q. Look at page 428, please. 24 A. 428? 25 Q. Yes. And you see on the right-hand</p>
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<p>1 A. Yep. 2 Q. And the citation down below cites, for 3 that assertion, pages 145, 149, 151 and 164 to 165, 4 correct? 5 A. Yes. That's what it reads. 6 Q. And it's your contention in your expert 7 report that those pages stand for the proposition that 8 we just read the "natural talc formation is commonly 9 accompanied by veins of other minerals, including 10 asbestiform minerals like tremolite and serpentine," 11 correct? 12 A. Yes. 13 Q. Let's move on because I'm not sure I have 14 it time to sit and read them all now. Let's move on to 15 another topic. Let's look at page 9 of your report, 16 please. 17 A. Page 9? 18 Q. Page 9, sir, yes. And do you see on page 19 9 that you have said in the -- I think it's the second 20 full paragraph. "Based on what I have reviewed, I have 21 sufficient basis to conclude that Italian ore was of 22 poor quality," correct? 23 A. Yes. 24 Q. And let me show you, first of all, an 25 exhibit that we'll mark as Exhibit 24.</p>	<p>1 column, this is a paragraph that has "Talc" in bold at 2 the beginning of the paragraph, correct? 3 A. Correct. 4 Q. And it says -- and I won't try to 5 pronounce the Italian names. We had enough trouble with 6 Chinese names earlier on, but "Talc" -- I'll try -- "e 7 Grafite Val Chisone S.p.A. operated two underground 8 mines at Pinerolo near Turin," correct? 9 A. That is what it says. I didn't know. 10 Q. And next sentence says, "The white talc, 11 mined from metamorphic rocks, has been of very high 12 quality," correct? 13 A. That is what it says. It doesn't say 14 what high quality for. Is it -- the table in the back, 15 does it say what the talc is used for? Talc and related 16 materials. It just lists tonnages. 17 MR. FERGUSON: And I'd like the next 18 list, Exhibit 24 -- 25. My bad. 19 (Exhibit 25 was marked for 20 identification.) 21 BY MR. FERGUSON: 22 Q. The first author is Edward B. Ilgren, 23 I-l-g-r-e-n, correct? 24 A. Ilgren, yes. 25 Q. And the title is "Analysis of an</p>

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<p>1 Authentic Historical Italian Cosmetic Talc Sample</p> <p>2 Further Evidence for the Lack of Cancer Risk," correct?</p> <p>3 A. And analysis of an, implying one,</p> <p>4 authentic historical Italian. Yes, that's what the</p> <p>5 title is.</p> <p>6 Q. Exactly. It does say "an," a-n?</p> <p>7 A. A single or it's implied that's a single</p> <p>8 sample. I have not seen this paper before.</p> <p>9 Q. Can you look with me at the first line of</p> <p>10 the abstract, where it says, "Italian talc from the</p> <p>11 Pinerolo Mines in northwest Italy is known for its</p> <p>12 extreme purity," correct?</p> <p>13 A. That is what it says. It doesn't say</p> <p>14 with respect to what, so and then -- so it's an</p> <p>15 abstract. It should be a summary from introductory</p> <p>16 materials, so let's see if they discuss that in the</p> <p>17 introduction. "It is known for its extreme purity.</p> <p>18 More than 60 years of epidemiological studies have</p> <p>19 failed to demonstrate any attendant cancer risk." So --</p> <p>20 Q. I don't need you to read it out loud. I</p> <p>21 apologize for interrupting. Obviously, time is limited.</p> <p>22 You've answered my question, so what we know is that</p> <p>23 Mr. Newman and Dr. Ilgren disagree with your comment</p> <p>24 that the Italian talc is not good quality, correct?</p> <p>25 MS. O'DELL: Object to the form.</p>	<p>1 about his report while you're pulling that up,</p> <p>2 if you wouldn't mind?</p> <p>3 MS. O'DELL: Yeah, sure. I've got it</p> <p>4 right here.</p> <p>5 BY MR. FERGUSON:</p> <p>6 Q. Could look at page 31 of your report,</p> <p>7 Dr. Krekeler?</p> <p>8 A. I'm at page 31.</p> <p>9 Q. Are you with me, sir? Okay. Just above</p> <p>10 the heading of "Toxic Metal Contamination," is a</p> <p>11 paragraph that starts "In summary." And do you see a</p> <p>12 sentence there that says, "Defendants admit that the</p> <p>13 beneficitation process does not remove asbestos"? Do you</p> <p>14 see that sentence?</p> <p>15 A. I do see that sentence.</p> <p>16 Q. And for that proposition, you cite the</p> <p>17 deposition of Patrick Downey at page 407, pages -- line.</p> <p>18 Excuse me. Lines 13 through 16, correct? That's what</p> <p>19 you cited?</p> <p>20 A. Correct.</p> <p>21 Q. All right. Let's look, if we may, look</p> <p>22 at Exhibit 26, and the second -- the first page of that</p> <p>23 is just the cover page to Mr. Downey's deposition.</p> <p>24 Could you turn to the second page, and let's look at</p> <p>25 page 407, lines 13 to 16, which you cited.</p>
Page 291	Page 293
<p>1 A. They can disagree, correct.</p> <p>2 BY MS. ROSE:</p> <p>3 Q. At one point in your report on page 13,</p> <p>4 you say that, "Usually, companies have a dedicated</p> <p>5 in-house laboratory for these analyses."</p> <p>6 A. Yes. Oil Dry as an example. There's</p> <p>7 other companies that have, you know, extensive labs, and</p> <p>8 also, people rely on third-party labs to check their</p> <p>9 internal labs.</p> <p>10 Q. And you're aware that Imerys has had and</p> <p>11 has a dedicated in-house laboratory as well, correct?</p> <p>12 A. I believe so, yes.</p> <p>13 Q. And, in addition, Imerys has had occasion</p> <p>14 to send samples to third-party laboratories as well,</p> <p>15 correct?</p> <p>16 A. Correct.</p> <p>17 Q. Let me mark for you Exhibit 26 to your</p> <p>18 deposition, please.</p> <p>19 (Exhibit 26 was marked for</p> <p>20 identification.)</p> <p>21 MS. O'DELL: Let me get that out here.</p> <p>22 MR. FERGUSON: Sure. No problem. Let me</p> <p>23 know when you're ready.</p> <p>24 MS. O'DELL: Yeah. Okay.</p> <p>25 MR. FERGUSON: Can I ask him a question</p>	<p>1 A. So 407?</p> <p>2 Q. Yes, sir.</p> <p>3 A. 13 to 16. Can I have a moment to read</p> <p>4 the context above it and stuff?</p> <p>5 Q. Certainly, sir.</p> <p>6 A. To refresh my memory?</p> <p>7 Q. Certainly, sir. Ready to go? Got the</p> <p>8 context?</p> <p>9 A. Yes.</p> <p>10 Q. All right. So if we look at lines 13</p> <p>11 through 16, that is an answer by Mr. Downey where he</p> <p>12 says, "I don't know if -- I'm not familiar, and I don't</p> <p>13 know if flotation was intended to remove asbestos, but</p> <p>14 to my knowledge, our products don't contain asbestos</p> <p>15 so." Did I read that correctly?</p> <p>16 A. Yes, you did read that correctly.</p> <p>17 Q. So, in fact, Mr. Downey is not, as you</p> <p>18 say, admitting that the beneficitation process does not</p> <p>19 remove asbestos. Instead, what he says is I don't know</p> <p>20 if flotation was intended to remove asbestos, correct?</p> <p>21 A. That's what it says. I took it as -- he</p> <p>22 said "I don't know" twice, "I'm not familiar." And it</p> <p>23 says, "I don't know if flotation was intended to remove</p> <p>24 asbestos." So the text is correct, yes.</p> <p>25 Q. But you would agree he did not admit that</p>

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<p style="text-align: right;">Page 294</p> <p>1 the beneficiation process does not remove asbestos, 2 correct?</p> <p>3 MS. SCOTT: Objection.</p> <p>4 A. He doesn't know if it was intended or not 5 is how -- that's how I interpret it. Others can 6 interpret it in other ways.</p> <p>7 BY MR. FERGUSON:</p> <p>8 Q. Would you look at the bottom of page 31, 9 please, of your report?</p> <p>10 A. Okay. On page 31. I see it, yes.</p> <p>11 Q. And you see it says, at the bottom, it 12 starts a sentence, "In fact, these chemical elements are 13 inherent properties of talc ore, a fact acknowledged by 14 Julie Pier in her deposition." And then you cite Julie 15 Pier Deposition, page 211, lines six through 13 from the 16 September 12, 2018, session of her deposition. Do you 17 see that?</p> <p>18 A. Yes, I do.</p> <p>19 Q. And could you go to your left and pick up 20 Miss Pier's deposition? And both sessions are there. 21 If you could, look at the -- they're in reverse order, I 22 noticed before, so would you look at the deposition that 23 is the second one in that notebook? It's the second 24 one. It's not the first one because they're in reverse 25 order. That's the September 13 session, I notice, and</p>	<p style="text-align: right;">Page 296</p> <p>1 A. I have -- "I have just a general broad 2 understanding that as it's crushed, an automatic sampler 3 takes a sample at specific time intervals." That's 4 through line 13.</p> <p>5 Q. All right. So would you agree with me 6 that in that portion of the deposition, Ms. Pier does 7 not acknowledge the fact that chemical elements are 8 inherent properties of talc ore, correct?</p> <p>9 A. Correct.</p> <p>10 Q. It doesn't say that at all, does it?</p> <p>11 A. Yeah. I must have made a mistake with 12 the numbering.</p> <p>13 Q. You also state in your report that Imerys 14 admitted in depositions that -- well, let me skip back 15 because I don't have my citation. So let's -- let's 16 move on to another topic. I may come back to that if I 17 have time, okay?</p> <p>18 A. Right. Do you want me to put the Pier 19 deposition away?</p> <p>20 Q. Yeah, for now.</p> <p>21 A. I'll set it aside.</p> <p>22 Q. Yeah. Keep it handy in case we have time 23 to get back to that.</p> <p>24 A. Okay.</p> <p>25 Q. Now, you have taken, as you -- as we</p>
<p style="text-align: right;">Page 295</p> <p>1 you can go all the way past those. There you go.</p> <p>2 A. I'll try not to break the stuff.</p> <p>3 Q. Can we look at page --</p> <p>4 A. You said -- is it 211?</p> <p>5 Q. Yes, sir. Page 211, please, sir.</p> <p>6 A. I turned right to it. 211.</p> <p>7 Q. Okay.</p> <p>8 A. And you're interested in lines 6 through 9 13? Is that your question?</p> <p>10 Q. Right. And what you've asserted is 11 that -- you cite that for the proposition, "In fact, 12 these chemical elements are inherit properties of talc 13 ore, a fact acknowledged by Julie Pier."</p> <p>14 Can you read for me page 211, Lines 6 15 through 13 of the September 12 deposition?</p> <p>16 A. Well, this has to do -- can I first read 17 the context a little bit to refresh myself?</p> <p>18 Q. Right now, I'd like you to read what --</p> <p>19 A. Okay. I can just read the text.</p> <p>20 Q. Yeah, what you cited.</p> <p>21 A. "Well, this has to do with sampling 22 that's done at the operation. I'm thinking that Pat is 23 in -- If you don't know, you can tell me that." 24 Question. "I'm" -- dash dash dash or -- ". . ." 25 Q. Are you past line --</p>	<p style="text-align: right;">Page 297</p> <p>1 discussed earlier, you have taken the report of 2 Drs. Longo and Rigler and relied upon it for your 3 report, correct?</p> <p>4 A. Correct.</p> <p>5 Q. And that has to do with whether there are 6 contaminants in talc that is sold by Imerys and by 7 Johnson & Johnson, correct? That's what they addressed?</p> <p>8 A. Correct.</p> <p>9 Q. Now, are you an aware, Dr. Krekeler, that 10 the United States Food & Drug Administration actually 11 performed a survey of talc and body powders and cosmetic 12 raw material talc?</p> <p>13 A. I believe so. I looked at an FDA 14 document on the Internet, and if I remember correctly -- 15 I would want to check -- there was four suppliers that 16 provided talc products, and they did not find any 17 indications or it was nondetects for those many samples. 18 But I also remember that the FDA also said that -- I'd 19 have to look at it for the exact language, but, 20 essentially, the FDA couldn't fully assure that talc is 21 free of asbestos, I think. Do you have that?</p> <p>22 MR. FERGUSON: Yeah. Let's go ahead and 23 mark as Exhibit 27 the FDA survey. 24 (Exhibit 27 was marked for 25 identification.)</p>

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<p>1 A. I don't know if it's exactly the same one 2 that I looked at. 3 MR. BILLINGS-KANG: Ken, was the Pier 4 deposition marked at all? 5 MR. FERGUSON: No. I didn't mark it. I 6 can mark it. 7 MS. SCOTT: 27? 8 MR. FERGUSON: Yes. 9 A. It's a printed, so it looks like a 10 different format than maybe the one I looked at. The 11 tables look familiar. 12 BY MR. FERGUSON: 13 Q. So since our time is growing short, if 14 you would, it looks familiar? 15 A. Okay. Yeah. I -- I do think it's the 16 one I looked at, I think. 17 Q. Go to the second page of the exhibit, and 18 you see that it has a heading and a little chart saying 19 "Cosmetic-grade raw material talc," correct? 20 A. The second page, the heading is "How FDA 21 followed up on the latest"? 22 Q. Yeah. If you go to the bottom, there's a 23 little chart with a heading that says, "Cosmetic-grade 24 raw material talc," correct? 25 A. Yes.</p>	<p>1 Q. Let's call it rows. 2 A. Oh, rows. Okay. All right. 3 Q. Okay. 4 A. So for these seven rows, yes. 5 Q. Okay. 6 A. There's no asbestos detected for those 7 seven samples. 8 Q. Okay. And if we go to the 9 second-to-the-last page of that exhibit -- in fact, it's 10 the last page that has typing on it. 11 A. The second-to-the-last page. 12 Q. Are you there? 13 A. Okay. 14 Q. Do you see there's a column that is or a 15 chart that is entitled "Body Powder," correct? 16 A. Correct. 17 Q. And there's a line, a row for Johnson's 18 Baby Powder, correct? 19 A. Correct. 20 Q. That says no asbestos detected by PLM or 21 by TEM, correct? 22 A. Correct. 23 Q. And a row for Shower or Shower, Morning 24 Fresh Absorbent Body Powder that likewise says no 25 asbestos detected by PLM and TEM, correct?</p>
Page 299	Page 301
<p>1 Q. And you see under "Supplier," it says, 2 "Rio Tinto Minerals/Luzenac America," correct? 3 A. Correct. 4 Q. And if you look at that and the next 5 page, there are seven lots that were tested from Rio 6 Tinto Minerals/Luzenac America, correct? 7 A. One, two, three, four. Yes. Seven? 8 Q. Yes, sir. 9 A. From Rio Tinto. 10 Q. Okay. And there's a column for 11 "Percentage Asbestos by PLM." That's polarized light 12 microscopy, correct? 13 A. Yes. There's a column for that. 14 Q. And there's a percentage asbestos by TEM 15 or transmission electron microscope, correct? 16 A. Yes. There's a column for that. 17 Q. Okay. And in all 14 columns, it notes no 18 asbestos detected, correct? 19 MS. O'DELL: Objection. 20 A. Fourteen columns? 21 BY MS. ROSE: 22 Q. Well, there's seven for PLM, seven for 23 TEM? 24 A. Oh, you mean rows or 14 columns? One, 25 two, three, four, five columns.</p>	<p>1 A. At the very bottom, yes. 2 Q. So in this Food & Drug Administration 3 survey that was done, the results were different than 4 the ones that Drs. Longo and Rigler came up with, 5 correct? 6 MS. O'DELL: Object to the form. 7 A. Well, it's not the same sample size. 8 And, yeah, this is the same report. As it says, "For 9 these reasons, while FDA finds these results 10 informative, they do not prove that most or all talc or 11 talc-containing cosmetic products currently marketed in 12 the United States are likely to be free of asbestos 13 contamination. As always, when potential" -- yeah. 14 This is, yeah. This is the, yeah. 15 BY MS. ROSE: 16 Q. But we know that they tested Luzenac, raw 17 material talc and Johnson & Johnson body powder, 18 correct? 19 A. Correct. Yes. 20 MR. FERGUSON: What are we doing on time, 21 if you wouldn't mind letting me know? 22 VIDEOGRAPHER: You've been on record six 23 hours and 51 minutes. 24 MR. FERGUSON: I've got a few minutes. 25 MR. BILLINGS-KANG: Plenty of time.</p>

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<p>1 MR. FERGUSON: Plenty of time.</p> <p>2 THE WITNESS: Are we done with this one?</p> <p>3 MR. FERGUSON: Yes, sir. We're done with</p> <p>4 that one.</p> <p>5 BY MS. ROSE:</p> <p>6 Q. Let me ask you one more area, one more</p> <p>7 area, and then I'll quit.</p> <p>8 MR. BILLINGS-KANG: I'm going to give him</p> <p>9 my time.</p> <p>10 MR. FERGUSON: Okay.</p> <p>11 MR. CARY: Time for the gentleman from</p> <p>12 Texas.</p> <p>13 MS. O'DELL: It's like we're in the</p> <p>14 Senate or House.</p> <p>15 MR. FERGUSON: The House. I hope not.</p> <p>16 MR. FROST: Won't do too well for that.</p> <p>17 MS. SCOTT: I was just going to say the</p> <p>18 same thing.</p> <p>19 BY MR. FERGUSON:</p> <p>20 Q. Could you get the IARC 93 monograph,</p> <p>21 which I believe is Exhibit 5?</p> <p>22 A. IARC 93. IARC 93. Yep. Exhibit 5, yes.</p> <p>23 Q. All right.</p> <p>24 MR. FERGUSON: And I'm sorry, Leigh and</p> <p>25 Carmen, do you guys have? Okay.</p>	<p>1 jet mills and are classified and separated from other</p> <p>2 minerals by froth flotation or magnetic separation,"</p> <p>3 correct?</p> <p>4 A. Yes. And there's no citation for that.</p> <p>5 Q. And the IARC working group does note that</p> <p>6 the techniques by which top ores may be processed</p> <p>7 include hand sorting, correct?</p> <p>8 A. Correct, yes. That's in the second line</p> <p>9 on the paragraph. That's what they say. Again, it's</p> <p>10 not cited, so I'm not sure where they get the</p> <p>11 information from, but they say that.</p> <p>12 MR. FERGUSON: Can we go off for one</p> <p>13 second? I know we're almost done, please.</p> <p>14 VIDEOGRAPHER: We're now going off</p> <p>15 record. The time is 7:05.</p> <p>16 (Off the record.)</p> <p>17 VIDEOGRAPHER: We are now back on record.</p> <p>18 The time is 7:07.</p> <p>19 BY MR. FERGUSON:</p> <p>20 Q. Dr. Krekeler, could you turn to page 42</p> <p>21 of your report?</p> <p>22 A. 42 of my report?</p> <p>23 Q. Yes, sir.</p> <p>24 A. 42.</p> <p>25 Q. Not of the IARC.</p>
Page 303	Page 305
<p>1 MS. O'DELL: What page?</p> <p>2 MR. FERGUSON: I am going to be looking</p> <p>3 at page 286.</p> <p>4 BY MR. FERGUSON:</p> <p>5 Q. Can you find page 286?</p> <p>6 A. 286. 285, 286. I found it.</p> <p>7 Q. At the top of page 286, the section --</p> <p>8 and, again, this is from the IARC monograph, correct?</p> <p>9 A. Correct.</p> <p>10 Q. That you discussed earlier and you've</p> <p>11 cited in your report, correct?</p> <p>12 MS. O'DELL: Objection. Cites the</p> <p>13 monograph, but you're saying he cites this.</p> <p>14 It's a little confusing.</p> <p>15 MR. FERGUSON: I apologize.</p> <p>16 BY MR. FERGUSON:</p> <p>17 Q. You've cited this monograph, not</p> <p>18 necessarily this portion of it?</p> <p>19 A. Correct. Yeah. I've cited the</p> <p>20 monograph.</p> <p>21 Q. So let's look at the first paragraph</p> <p>22 there on page 286. You see it says, "Talc ores may be</p> <p>23 processed by a variety of techniques that include</p> <p>24 selective mining, hand sorting and milling by roller</p> <p>25 mills, hammer mills, ball mills, fluid energy mills and</p>	<p>1 A. Oh, I thought we were still talking about</p> <p>2 that. I'm sorry.</p> <p>3 Q. No. I apologize. Of your report?</p> <p>4 A. Okay.</p> <p>5 Q. Okay?</p> <p>6 A. Yep.</p> <p>7 Q. Are you there?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. So if you look at the last</p> <p>10 paragraph on page 42 about --</p> <p>11 A. Grinding?</p> <p>12 Q. That paragraph.</p> <p>13 A. Yep.</p> <p>14 Q. But if you look at the fifth line of</p> <p>15 that, you see where it starts, "Imerys admitted," and it</p> <p>16 goes on to say, "Imerys admitted, in deposition, that a</p> <p>17 phyllosilicate sample could be ground to a near</p> <p>18 amorphous state, damaging the sample, even with minimal</p> <p>19 grinding." Correct? Did I read that correctly?</p> <p>20 A. Yes. That is correct.</p> <p>21 Q. And then you cite the Julie Pier</p> <p>22 deposition, page 25, 23 to 25, and page 26, 1 through</p> <p>23 23, September 23rd, 2018? Correct?</p> <p>24 A. Correct.</p> <p>25 Q. And so would you pick up again the Julie</p>

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<p style="text-align: right;">Page 306</p> <p>1 Pier notebook to your left? And this time, we're 2 looking at the first deposition in the notebook because 3 they're reversed, and that's the September 13th, 2018, 4 date. So would you turn to page 25 in that 5 deposition -- 6 A. This starts at page 340. 7 Q. Yes, it does. 8 A. So page -- 9 Q. Would you with agree with me there is no 10 page 25 and no page 26 in the Julie Pier deposition 11 transcript from September 13th, 2018? 12 A. I don't know. 13 Q. Well -- 14 A. Let's look and see. 15 Q. You have the deposition transcript in 16 front of you, sir. 17 A. Is that -- I don't remember if it's a one 18 or two volume. Some of these, I think, were two volume. 19 Q. Well, sir -- 20 A. So I think if -- yeah, I don't remember 21 specifically, but if this is -- 22 Q. Why don't you look at the very first 23 page. 24 A. The first page says 340. This is the 25 page number.</p>	<p style="text-align: right;">Page 308</p> <p>1 Q. Well, those pages weren't missing. The 2 words that you quoted were not just not on them, 3 correct? 4 MS. SCOTT: Objection. 5 A. It's unclear. 6 BY MR. FERGUSON: 7 Q. Do you think maybe this is another 8 mistake or typo? 9 A. I don't know. 10 MR. FERGUSON: That's all I have, 11 Dr. Krekeler. Thank you for your time, sir. 12 VIDEOGRAPHER: Do you want to go off? 13 MS. O'DELL: James, are you okay? 14 MR. BILLINGS-KANG: I'm fine. Thank you. 15 MS. O'DELL: How much time on the record? 16 VIDEOGRAPHER: Seven hours even. 17 MS. O'DELL: Let's go take a break. 18 MR. FROST: Look at that. 19 VIDEOGRAPHER: We are going off record. 20 The time is 7:13. 21 (A recess was taken from 7:13 to 7:47.) 22 VIDEOGRAPHER: We are now back on record. 23 The time is 7:47. 24 EXAMINATION 25</p>
<p style="text-align: right;">Page 307</p> <p>1 Q. Look at the very first page there that 2 you're looking at there, and does that say Julie Pier's 3 deposition from September 13th of 2018? 4 A. Actually, on this page, there is not -- 5 oh, September 13th, 2018. 6 Q. And just as you told us, there is no page 7 25 or page 26 for the September 13, 2018, deposition of 8 Julie Pier, is there? 9 A. In this printed copy, there appears not 10 to be. I don't -- 11 Q. So -- 12 A. Can I check to see if it's confused by -- 13 just double-check? I might have. 14 Q. Do you want to check the September 12th 15 version and see? 16 A. Yeah. I don't know if I've confused 17 things or not. So we're looking at -- 18 Q. Page 25 and page 26. 19 A. 25 and 26. 20 Q. She is not talking about phyllosilicates 21 on pages 25 or 26 of the September 12th, is she? 22 A. Correct. I currently don't have an 23 explanation for the apparent discrepancy. 24 Q. Do you think since -- 25 A. I don't know if pages are missing or...</p>	<p style="text-align: right;">Page 309</p> <p>1 BY MS. O'DELL: 2 Q. Dr. Krekeler, good evening. I've got a 3 few questions for you to follow up. 4 A. Okay. 5 Q. First, you were asked a number of 6 questions about Italian talc and the talc ore deposits 7 in Italy. Do you recall those questions? 8 A. Generally, yes. 9 Q. And, in fact, you were handed a binder of 10 a documents that I think are in front of you now that -- 11 they were marked as Exhibit 14. 12 A. Exhibit -- yes. 13 Q. And they related to certain documents 14 regarding talc formations in Italy. Do you recall those 15 documents? 16 A. Correct. 17 Q. And specifically in terms of the Italian 18 ore bodies, were there positive tests of asbestos in 19 Italian talc that you reviewed in reaching your opinions 20 in this case? 21 MR. FROST: Objection to form. 22 A. Yes. 23 BY MS. O'DELL: 24 Q. And, in fact, if you'll turn to page -- I 25 think it was 14 of your report. Do you see that?</p>

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<p>1 A. Yes.</p> <p>2 Q. And are the test results depicted on page</p> <p>3 14 -- well, let me just ask you this way. Where did the</p> <p>4 test results depicted in the table on page 14 of your</p> <p>5 expert report, where did they originate from?</p> <p>6 A. There are five examples from 1957 to '58</p> <p>7 from Italy.</p> <p>8 Q. And you were also handed by Mr. Ferguson</p> <p>9 what's been marked as Exhibit 25. I don't recall if you</p> <p>10 recall a document entitled, "Analysis of an Authentic</p> <p>11 Historical --</p> <p>12 A. Yes.</p> <p>13 Q. -- "Italian Cosmetic Talc Sample." Do</p> <p>14 you recall that?</p> <p>15 A. Yep.</p> <p>16 Q. Do you have it in front of you?</p> <p>17 A. Yes.</p> <p>18 Q. And Mr. Ferguson asked you to read the</p> <p>19 first sentence of the abstract which addressed "the</p> <p>20 extreme purity" of Italian talc. Do you recall that?</p> <p>21 A. Correct. Yes, I do.</p> <p>22 Q. Did this report that's been marked as</p> <p>23 Exhibit 5 actually report the presence of tremolite</p> <p>24 fibers in Italian talc?</p> <p>25 A. Yes. There's -- it reports the numerical</p>	<p>1 BY MS. O'DELL:</p> <p>2 Q. In fact, at the top, in the first full</p> <p>3 paragraph, it says, "The TEM micrograph in Figure B1</p> <p>4 shows a number of platy talc particles. Figure B-2</p> <p>5 shows platy talc particles and an elongated fragment of</p> <p>6 talc."</p> <p>7 A. Of talc. Two -- yeah. "Two other</p> <p>8 tremolite fibers were detected," and then it restates</p> <p>9 that numerical concentration of tremolite fibers in talc</p> <p>10 was the number that I mentioned previously.</p> <p>11 BY MS. O'DELL:</p> <p>12 Q. And so does, in fact, Exhibit 25 support</p> <p>13 your opinion that Italian talc is contaminated with</p> <p>14 asbestos?</p> <p>15 MR. BILLINGS-KANG: Objection to form.</p> <p>16 MR. FROST: Objection to form.</p> <p>17 BY MS. O'DELL:</p> <p>18 Q. Now, let me ask you to turn to your</p> <p>19 report specifically. Oh, one question. You were asked</p> <p>20 a few questions today about the beneficiation process,</p> <p>21 and if there is asbestos fibers present in talc ore, is</p> <p>22 there anything in the beneficiation process that you</p> <p>23 would expect to remove the asbestos fibers from the</p> <p>24 talc?</p> <p>25 A. Not efficiently.</p>
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<p>1 concentration of tremolite fibers in the talc sample was</p> <p>2 3.67 -- 3.687 times 10 to the negative 6 fibers per</p> <p>3 gram, so that is over 3 million fibers per gram</p> <p>4 corresponding to a mass concentration of .722 parts per</p> <p>5 million.</p> <p>6 Q. And if you'll turn to page 3 of this</p> <p>7 exhibit --</p> <p>8 MR. FROST: Leigh, what exhibit is this?</p> <p>9 MS. O'DELL: 25.</p> <p>10 MR. FROST: 25. Okay.</p> <p>11 MS. O'DELL: It's what Ken marked.</p> <p>12 MR. FROST: Oh, I thought you said five.</p> <p>13 I apologize.</p> <p>14 MS. O'DELL: Did I? Sorry. Thank you.</p> <p>15 MR. BILLINGS-KANG: You said five.</p> <p>16 MS. O'DELL: I don't think you heard the</p> <p>17 two, but 25 is what I'm referring to.</p> <p>18 MR. FROST: Thank you.</p> <p>19 BY MS. O'DELL:</p> <p>20 Q. On page 3 of the exhibit, Dr. Krekeler,</p> <p>21 did the authors of this report also report the presence</p> <p>22 of fibrous talc in this particular sample?</p> <p>23 MR. BILLINGS-KANG: Object to form.</p> <p>24 A. Yes. I believe I saw it in here.</p> <p>25</p>	<p>1 Q. Let me ask you to turn to page 35 of your</p> <p>2 report. Actually, 36.</p> <p>3 A. Okay. I'm on page 36.</p> <p>4 Q. And, actually, you can look at, actually,</p> <p>5 either 35 or 36, but are the test results and the</p> <p>6 samples that are of the samples reported in the table on</p> <p>7 page 35, and do many of them include the results of</p> <p>8 annual composite samples?</p> <p>9 A. Yes.</p> <p>10 Q. And are -- what are annual composite</p> <p>11 samples?</p> <p>12 A. They are, essentially, talcum powder</p> <p>13 that's ready to go as a consumer product, essentially a</p> <p>14 consumer product.</p> <p>15 Q. And annual samples would be composed of</p> <p>16 processed talc?</p> <p>17 A. Yes.</p> <p>18 Q. And let me ask you to look at page 36,</p> <p>19 where you report some of the findings regarding</p> <p>20 chromium. Did Johnson & Johnson conduct testing of its</p> <p>21 talc powder that was specific enough to identify whether</p> <p>22 the type of chromium contained was either hexavalent</p> <p>23 chromium or trivalent chromium?</p> <p>24 MR. BILLINGS-KANG: Objection to form.</p> <p>25 MR. FROST: Objection to form.</p>

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<p>1 A. No. I saw no evidence of any testing to 2 determine whether chromium was in the three-plus state 3 or the six-plus state. 4 MR. FROST: Move to strike the response 5 as speculative. 6 BY MS. O'DELL: 7 Q. Is that also true -- is that also true of 8 the testing that was conducted by Imerys? 9 MR. FROST: Objection to form. 10 A. I'm sorry. Can you repeat the question? 11 BY MS. O'DELL: 12 Q. Is that -- is that also true of the 13 testing that was conducted by Imerys regarding chromium? 14 MR. FROST: Same objection. 15 A. Yes. 16 BY MS. O'DELL: 17 Q. You were asked a number of questions 18 regarding the ore deposits in Vermont. Do you recall 19 those questions? 20 A. Yes. 21 Q. And you -- one of the exhibits that was 22 marked in regard to Vermont was the Ross commentary that 23 you cited, and I believe it's in front of you. What's 24 the exhibit number, please? 25 A. Twelve, I think.</p>	<p>1 geologic terrain. 2 Q. And in the comments that are included in 3 the Ross paper would cover the geologic formations that 4 were used to source Johnson & Johnson's talcum powder in 5 Vermont? 6 A. Yes. 7 MR. FROST: Objection to form. Calls for 8 speculation. 9 BY MS. O'DELL: 10 Q. Let me ask you to turn to Exhibit 11, 11 which should be right -- 12 A. Eleven. 13 Q. -- in front of you there. 14 A. Yes. 15 Q. And if you'll turn to page 2 of -- 16 A. Page 921 in the article? 17 Q. Yes. Let me ask you, with the 18 constituents of the geology, geologic formation that is 19 described in Ross, and we'll get to it, but, also, in 20 Van Gosen, would those constituents, as described in 21 those publications, be the same or similar to the mines 22 in Vermont that were used to source Johnson & Johnson's 23 talcum powder? 24 MR. FROST: Objection to form. 25 A. Yes.</p>
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<p>1 Q. Okay. 2 A. That's correct. 3 Q. And Exhibit 12 was a reference that you 4 cited in your report? 5 A. Correct. 6 Q. And is the Ross commentary supportive of 7 your opinions? 8 A. Yes. 9 Q. Why? 10 A. So, essentially, end of second column, 11 "Ultramafic talc deposits of Vermont offer a third 12 example of the complexities of rock formations 13 containing asbestos minerals. The core of the 14 ultramafic bodies is off a serpentine rock derived from 15 a hydrothermal alteration of a pre-existing pyroxene and 16 olivine-rich ultramafic rock. The serpentine core often 17 grades outward into talc-serpentine-carbonate rock, then 18 steatite (massive talc ore containing often small 19 amounts of serpentine), then 'blackwall' rock (contains 20 amphiboles, chlorite, quartz, albite, et cetera), and 21 finally the country rock. Equivalent ultramafic bodies 22 in Quebec, Canada, form some of the world's largest 23 chrysotile deposits." 24 So, essentially, this is all the talc 25 mines are all part of this one essentially extensive</p>	<p>1 BY MS. O'DELL: 2 Q. Let me ask you to turn specifically to 3 Van Gosen, which we've marked as Exhibit 11 and 4 specifically ask you to turn to page 933. 5 A. Okay. Yes. 6 Q. Does page 933 begin a description of 7 Vermont talc? 8 A. Yes, it does. 9 Q. Does this description by Van Gosen apply 10 to the, or is it relevant to the geology of the talc 11 mines that were used to source J&J talc? 12 A. Yes, it is. 13 MR. FROST: Objection. Calls for 14 speculation. 15 BY MS. O'DELL: 16 Q. And if you'll turn to page 934, what is 17 the description of the Vermont talc geology that Van 18 Gosen includes in his article? 19 A. So, sorry. On the previous page, the 20 alteration of zones are typically compromised by 21 sequence, provides details -- 22 Q. Doctor, read more clearly for the court 23 reporter, please. 24 A. "Ultramafic rocks, grading to a 25 talc-carbonate-dominant zone, grading to a nearly</p>

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<p>1 mono-mineralogical ... zone," all these other rich 2 zones, Items 1 through 7. And then "Black-wall talc 3 deposits are associated spatially with serpentinite 4 masses that, in some areas, host well-developed 5 chrysotile asbestos." And there's citations from 1942 6 and '63. 7 BY MS. O'DELL: 8 Q. Okay. And did it also say that some of 9 the alteration zones contain actinolite, tremolite and 10 anthophyllite? 11 A. Yes. 12 Q. And does the Van Gosen article support 13 your opinions in this case? 14 MR. FROST: Objection. Calls for 15 speculation. 16 A. Yes. 17 BY MS. O'DELL: 18 Q. Let me ask you now to turn to Exhibit 15, 19 which also should be in front of you. 20 A. Fifteen. 21 Q. It's the Chidester -- 22 A. Fourteen. 23 Q. Fifteen. 24 A. Okay. 25 Q. So the Chidester article that was</p>	<p>1 A. I had it somewhere. Yeah, 18. Yes. 2 Q. And if you'll turn in Exhibit 18 to page 3 11, is this a document that you relied on in reaching 4 your opinions? 5 A. Yes. I'll get to page -- 6 Q. Page 11. 7 A. Page 11, "Elemental Scan" at the top. 8 Q. And does this page address the presence 9 of certain heavy metals in Chinese talc deposits? 10 A. Yes. 11 Q. And what metals specifically were 12 elevated? 13 A. Titanium. 14 Q. And based on this document, does the 15 writer include a comment below regarding the need to -- 16 well, let me just say for the writer's comments below 17 regarding the presence? 18 A. "This very sophisticated analysis shows a 19 relatively wide array of elements in subtrace levels. 20 Other high grade talcs can show a similar array. The 21 analysis represents research information, which should 22 be conducted on a periodic basis to anticipate any 23 mineral contamination in future assessments of other 24 exposures of talc in the district." 25 Q. Let me ask you to put that aside, please,</p>
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<p>1 referenced earlier, and I'll ask you to turn to page 28. 2 If you'll turn -- 3 A. I am on page 28. 4 Q. Right. And does page 28 relate to the 5 Hammondsville talc mine? 6 A. Yes, it does. 7 Q. And was the Hammondsville talc mine one 8 of the mines that was used to source Johnson & Johnson's 9 talc? 10 A. Yes. 11 Q. And if you'll look on the right-hand 12 side, on the second paragraph, do you see that? 13 A. Yeah. "The deposit consists entirely of 14 coarse, flakey grit and of steatite. No serpentinite 15 has been found. In the southwestern face of the quarry, 16 there is a large mass of actinolite rock." 17 Q. Does that support your opinions in this 18 case? 19 A. Yes. 20 MR. FROST: Objection. Form. 21 BY MS. O'DELL: 22 Q. Let me ask you to set that aside and turn 23 to Exhibit 18. It's the document, the "Preliminary 24 Investigation of Cosmetic Talc Potential" in China, 25 Kwangsi, China. I think you had it in front of you.</p>	<p>1 sir. Thank you. 2 If you'll turn now to the IARC monograph, 3 which I think is on the '93 monograph, which is right 4 there. Yes. 5 A. This? Five? 6 Q. That's right, Exhibit 5. 7 A. Okay. 8 Q. You were asked a number of questions 9 about a statement that you made in your report about, I 10 think along the lines of it was common to find minerals 11 such as tremolite, anthophyllite, asbestos in talc 12 deposits. Do you recall those lines of questions? 13 A. Yes. 14 Q. And if you'll turn to page 284 of the 15 IARC monograph, 284, and this is the '93 monograph that 16 relates to talc not containing asbestiform fibers. If 17 you look at the bottom of 284, what does it say in the 18 IARC monograph regarding the presence of these minerals 19 in talc deposits? 20 A. It discusses minerals associated with 21 talc. "The most common minerals found in talc products 22 include chlorite, magnesite, dolomite, tremolite 23 anthophyllite, serpentine and quartz." 24 Q. And if you'll turn over to page 285, that 25 statement is further supported in Table 1.4?</p>

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<p>1 A. Yes.</p> <p>2 MR. FROST: Object to form.</p> <p>3 A. Tremolite is listed, anthophyllite is</p> <p>4 listed, actinolite is listed.</p> <p>5 BY MS. O'DELL:</p> <p>6 Q. And is that supportive of your opinion</p> <p>7 that those asbestos minerals are common in talc</p> <p>8 deposits?</p> <p>9 A. Yes.</p> <p>10 MR. FROST: Objection to form.</p> <p>11 BY MS. O'DELL:</p> <p>12 Q. Let me ask you just a general question</p> <p>13 first. How would you define fibrous talc?</p> <p>14 A. Fibrous talc is a talc particle that has</p> <p>15 a morphology consistent with the definition of a fiber.</p> <p>16 Q. And would it be fair to say that fibrous</p> <p>17 talc could be defined as talc formed in an asbestiform</p> <p>18 habit?</p> <p>19 MR. BILLINGS-KANG: Objection to form.</p> <p>20 MR. FROST: Objection to form.</p> <p>21 A. Yes.</p> <p>22 BY MS. O'DELL:</p> <p>23 Q. Let me ask you to look at Exhibit 22,</p> <p>24 Dr. Krekeler, which I think I had in front of you. It</p> <p>25 may be.</p>	<p>1 BY MS. O'DELL:</p> <p>2 Q. Dr. Krekeler, describe for us the</p> <p>3 methodology that you've used in reaching your opinions</p> <p>4 in this case.</p> <p>5 A. I evaluated data, I evaluated x-ray</p> <p>6 diffraction data, I evaluated core data, I evaluated</p> <p>7 electron microscopy data, I evaluated bulk chemistry</p> <p>8 data, I evaluated descriptions, I used peer-review</p> <p>9 literature, and these are essentially methods that would</p> <p>10 be expected if I was working as a consultant in a</p> <p>11 company.</p> <p>12 Q. Did you rely on published books regarding</p> <p>13 the geology of Vermont, Italy and China?</p> <p>14 A. Yes.</p> <p>15 Q. To the degree they were available?</p> <p>16 A. To the degree, yes. I would agree with</p> <p>17 that.</p> <p>18 Q. Is another common source that geologists</p> <p>19 rely on publications such as the U.S. Geological Survey?</p> <p>20 A. Yes.</p> <p>21 Q. And are there also publications from the</p> <p>22 U.S. Bureau of Mines?</p> <p>23 A. Yes.</p> <p>24 Q. And did you rely on those types of</p> <p>25 materials in reaching your opinions in this case?</p>
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<p>1 A. Twenty-two?</p> <p>2 Q. Yes.</p> <p>3 A. Okay.</p> <p>4 Q. And I would like for you -- you recall</p> <p>5 there was a number of documents that Mr. Frost showed</p> <p>6 you regarding six asbestos test results that were</p> <p>7 contained in the asbestos chart in your report beginning</p> <p>8 at page 14. Do you recall those questions?</p> <p>9 A. Yes.</p> <p>10 Q. And if I marked them correctly, Mr. Frost</p> <p>11 pointed out one, two, three, four, five, six test</p> <p>12 results that he took issue with. Do you recall that?</p> <p>13 A. Yes.</p> <p>14 Q. How many positive tests results, just</p> <p>15 estimate if you don't know --</p> <p>16 A. Approximately 125.</p> <p>17 Q. So let me -- and so let me ask you this</p> <p>18 question. Is there anything that you heard today that,</p> <p>19 in your mind, would call into question the veracity of</p> <p>20 the test results that, the other 125 test results that</p> <p>21 you reported in the chart, which begins in your report</p> <p>22 on page 14?</p> <p>23 MR. FROST: Objection to form.</p> <p>24 A. No.</p> <p>25</p>	<p>1 A. Yes.</p> <p>2 Q. Is the methodology that you used</p> <p>3 methodology that would be generally acceptable in the</p> <p>4 field of geology?</p> <p>5 A. Yes.</p> <p>6 MR. FROST: Objection to form.</p> <p>7 BY MS. O'DELL:</p> <p>8 Q. Did you rely on peer-reviewed literature</p> <p>9 to support your opinions?</p> <p>10 A. Yes.</p> <p>11 Q. Is peer-reviewed literature always</p> <p>12 available for specific mineral formations or deposits in</p> <p>13 geology?</p> <p>14 A. Not necessarily.</p> <p>15 Q. You were asked about the documents that</p> <p>16 you had received, internal documents that you had</p> <p>17 received in formulating your opinions in this case.</p> <p>18 Obviously, corporate documents were not available to you</p> <p>19 other than lawyers giving them to you, fair?</p> <p>20 A. Yes. Correct.</p> <p>21 Q. You didn't have an independent way to get</p> <p>22 the documents from Johnson & Johnson or Imerys in order</p> <p>23 to reach your opinions, right?</p> <p>24 A. Correct.</p> <p>25 Q. And did you feel that you had adequate</p>

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<p>1 materials to support the opinions contained in your 2 report? 3 MR. FROST: Objection to form. 4 MR. BILLINGS-KANG: Objection to form. 5 A. Yes. 6 BY MS. O'DELL: 7 Q. In terms of the testing documents that 8 are mentioned and reported in your expert report, are 9 testing documents something that you rely on in the 10 normal course of your role as a geologist? 11 A. Yes. 12 Q. Would that also be true of core logs? 13 A. Yes. 14 Q. And those are some of the documents that 15 you cited in your report? 16 A. Yes. 17 Q. Let me ask you just to talk just briefly 18 about your qualifications as a geologist. As a 19 geologist, are you -- do you teach the process of 20 evaluating mineral deposits? 21 A. Yes. I teach a course on ore deposits, 22 and I've taught courses on industrial minerology and 23 I've taught -- 24 Q. Excuse me. 25 A. When I was at George Mason, I would</p>	<p>1 particular order, but if we can first turn to the IARC 2 monograph. It's the one right in front of you there. 3 Which exhibit number is that? 4 A. I'm sorry. What? 5 Q. Which exhibit number is that? 6 A. Five. 7 Q. Okay. If you can turn to page 284. 8 A. Okay. 9 Q. So if you look at the bottom of the page, 10 Miss O'Dell had you read from the line starting, "The 11 most common minerals found in talc products," but before 12 that, it reads, "Because talc deposits are formed from 13 different protoliths under many different geological 14 conditions, each talc deposit has a combination of 15 mineralogy and mineral habit that is distinctive and, in 16 many cases, unique." Did I read that correctly? 17 A. There's no citation for that and, yes, 18 you did. 19 Q. Sir, my question is: Did I read that 20 correctly? 21 A. Yes. 22 Q. And that's what the IARC monograph says, 23 correct? 24 A. Correct. 25 Q. If you can turn to the Van Gosen article,</p>
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<p>1 regularly teach minerology. 2 Q. And would those courses have included 3 teaching students how to conduct expiration such as 4 drilling, core drilling and other ways to define an ore 5 deposit? 6 A. Yes. 7 MR. FROST: Object to form. 8 BY MS. O'DELL: 9 Q. Have you given presentations on those 10 types of activities? 11 A. Yes. 12 MS. O'DELL: Okay. I don't have anything 13 further. Thank you. 14 THE WITNESS: Okay. 15 MR. FROST: Could we go off the record? 16 VIDEOGRAPHER: Sure. We are now going 17 off record, and the time is 8:13. 18 (A recess was taken from 8:13 to 8:20.) 19 VIDEOGRAPHER: We are now back on record, 20 and the time is 8:20. 21 FURTHER CROSS-EXAMINATION 22 BY MR. FROST: 23 Q. All right, Doctor. A couple quick 24 follow-ups, and unfortunately, I'm going to run them in 25 the order they're in my binder, which probably is no</p>	<p>1 which is Exhibit 11. 2 A. Okay. 3 Q. Page 934. 4 A. All right. I'm on that page. 5 Q. Before, when you were reading this, you 6 skipped over most of Number 3. Number 3 reads, "a 7 nearly mono-mineralogical talc zone (often of high 8 purity) several centimeters to meters thick." Did I 9 read that correctly? 10 A. Yes. 11 Q. Do you agree with me that that would be 12 the talc ore zone, correct? 13 MS. O'DELL: Object to the form. 14 A. Presumably. A nearly -- a nearly 15 monomineralic -- mineralogical talc zone. 16 BY MR. FROST: 17 Q. Now, if we can turn to Exhibit 15, which 18 is the Chidst article -- Chidester. 19 A. 215. 20 Q. And specifically page 28. Okay. Counsel 21 had pointed you to the second paragraph, the second 22 column down, and you read the, "In the southwest face of 23 the quarry, there is large mass of actinolite rock," 24 correct? 25 A. Correct.</p>

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<p style="text-align: right;">Page 330</p> <p>1 Q. It doesn't say here that it's asbestos 2 actinolite, correct? 3 A. It does not specifically say that it's 4 asbestos. 5 Q. And you couldn't, without speculating, 6 based on this document, say whether or not it's 7 asbestos, correct? 8 MS. O'DELL: Object to the form. 9 A. I would agree. 10 BY MR. FROST: 11 Q. And then the sentence before that, the 12 end of it reads, No serpentine has been found; is that 13 correct? 14 A. No. It says, "No serpentinite." 15 Q. "No serpentinite," sorry, "has been 16 found"? 17 A. "Has been found." 18 Q. Okay. Sorry. I did read it incorrectly. 19 You are right. So "No serpentinite has been found"? 20 That's correct? 21 A. Correct. 22 MR. FROST: That's all questions I have, 23 sir. 24 VIDEOGRAPHER: Is that it? 25 MR. FERGUSON: I don't have any</p>	<p style="text-align: right;">Page 332</p> <p>1 CERTIFICATE 2 State of Ohio : 3 : SS 4 County of Hamilton : 5 I, Susan M. Gee, RMR, CRR, the undersigned, a 6 duly commissioned notary public within and for the State 7 of Ohio, do hereby certify that before the giving of his 8 aforesaid deposition, MARK KREKELER, Ph.D., was by me 9 first duly sworn to depose the truth, the whole truth 10 and nothing but the truth; that the foregoing is the 11 deposition given at said time and place by MARK 12 KREKELER, Ph.D.; that said deposition was taken in all 13 respects pursuant to stipulations of counsel; that I am 14 neither a relative of nor employee of any of their 15 parties or their counsel, and have no interest whatever 16 in the result of the action; that I am not, nor is the 17 court reporting firm with which I am affiliated, under a 18 contract as defined in Civil Rule 28(D). 19 IN WITNESS WHEREOF, I have hereunto set my 20 hand and official seal of office at Cincinnati, Ohio, on 21 this 29th day of January, 2019. 22 23 My commission expires: S/ Susan M. Gee, RMR, CRR 24 September 20, 2020. Notary Public - State of Ohio 25</p>
<p style="text-align: right;">Page 331</p> <p>1 questions. 2 MS. O'DELL: I have nothing further. 3 MR. FROST: All right. 4 VIDEOGRAPHER: This adjourns the 5 deposition of Dr. Mark Krekeler. We are now 6 going off record, and the time is 8:24. 7 COURT REPORTER: What about signature? 8 MS. O'DELL: Yes. 9 (Exhibit 28 through 30 were marked for 10 identification.) 11 - - - 12 DEPOSITION CONCLUDED AT 8:34 P.M. 13 - - - 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 333</p> <p>1 2 3 DECLARATION UNDER PENALTY OF PERJURY 4 5 Case Name: Talcum Powder Litigation 6 Name of Witness: Mark Krekeler, Ph.D. 7 Date of Deposition: January 25, 2019 8 9 I, MARK KREKELER, Ph.D., hereby certify under 10 penalty of perjury under the laws of the State of 11 _____ that the foregoing is true and correct. 12 Executed this _____ day of 13 _____, 2019, at _____. 14 15 16 17 MARK KREKELER, Ph.D. 18 19 20 21 22 23 24 25</p>

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<p style="text-align: right;">Page 334</p> <p>1 DEPOSITION ERRATA SHEET</p> <p>2 Case Name: Talcum Powder Litigation</p> <p>3 Name of Witness: Mark Krekeler, Ph.D.</p> <p>4 Date of Deposition: January 25, 2019</p> <p>5 Reason Codes: 1. To clarify the record.</p> <p>6 2. To conform to the facts.</p> <p>7 3. To correct transcription errors.</p> <p>8</p> <p>9 Page _____ Line _____ Reason _____</p> <p>10 From _____ to _____</p> <p>11 Page _____ Line _____ Reason _____</p> <p>12 From _____ to _____</p> <p>13 Page _____ Line _____ Reason _____</p> <p>14 From _____ to _____</p> <p>15 Page _____ Line _____ Reason _____</p> <p>16 From _____ to _____</p> <p>17 Page _____ Line _____ Reason _____</p> <p>18 From _____ to _____</p> <p>19</p> <p>20 _____ Subject to the above changes, I certify that</p> <p>21 the transcript is true and correct.</p> <p>22 _____ No changes have been made. I certify that the</p> <p>23 transcript is true and correct.</p> <p>24 _____</p> <p>25 MARK KREKELER, Ph.D.</p>	

A				
abandoned	65:14 66:2 70:19 153:13	adding	affect	208:10 210:7 212:14 213:13,15
215:5	accompanied	216:15	60:18 62:14,20	214:13 215:12
abiding	42:6 286:20 287:9	addition	137:15 231:13	220:9 222:14
234:16	accounts	56:20 157:2 164:8	276:17	228:20 230:4
ability	233:3	291:13	affiliated	231:15 234:6
196:2	accurate	additional	332:16	236:9 238:25
able	22:23,24 23:4,6,11	22:10 26:18 27:3,6	aforsaid	239:2 246:7
46:20 70:25 72:21	23:15,17 138:24	27:14 29:20 30:5	332:7	248:18 249:24
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257:17 266:6	achieve	address	224:22	269:18,25 270:14
abrade	95:22	209:22 320:8	age	272:7 273:2 275:3
74:22	acknowledge	addressed	8:12 62:1,3,3	275:6,10,22 281:5
abrasiveness	296:7	297:7 310:19	agency	281:21 293:25
164:6	acknowledged	adequate	174:25	296:5 306:9
absence	294:13 295:13	32:21 212:24 213:5	aggregate	324:16 329:11
219:4 220:15 221:4	acquired	325:25	76:5,22	330:9
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Exhibit 15

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

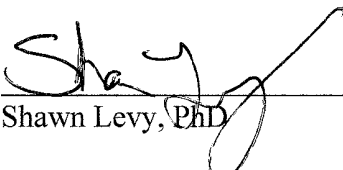
**IN RE JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES,
AND PRODUCTS LIABILITY
LITIGATION**

MDL NO. 16-2738 (FLW) (LHG)

THIS DOCUMENT RELATES TO ALL CASES

**RULE 26 EXPERT REPORT OF
SHAWN LEVY, PHD**

Date: November 16, 2018


Shawn Levy, PhD

I. Qualifications and Background

I am a founding director of and a faculty investigator with the Genomic Services Laboratory at the HudsonAlpha Institute for Biotechnology. My focus is on use of high performance genotyping and sequencing technologies as support for plant and animal phylogenetic studies and translational and clinical-based projects. A portion of my research entails using whole-genome sequencing to identify genetic markers associated with specific health conditions.

I serve as executive director of the HudsonAlpha Clinical Services Laboratory, LLC, which I launched in 2014. I am adjunct faculty in the department of genetics and department of epidemiology at the University of Alabama at Birmingham, adjunct faculty in the department of biological Sciences at the University of Alabama at Huntsville, and serve as an ad hoc reviewer for scientific journals including Nature, Nature Genetics, Science, Cell, Genome Research and several others. I have been a co-chair of the Genomics Working Group of the American Medical Informatics Association, a community of scientists and health care professionals that work to facilitate collaboration and share knowledge across a continuum, from basic and applied research to the consumer and public health arenas.

Prior to joining HudsonAlpha in 2009, I was a faculty member at Vanderbilt University Medical Center with appointments in the Department of Molecular Physiology and Biophysics and the Department of Biomedical Informatics. I was the founding director of the Vanderbilt Microarray Shared Resource where I served as Director for 9 years. I received my PhD in biochemistry and completed a postdoctoral fellowship in genetics at Emory University in Atlanta, where I set up a microarray facility at the Emory Center for Molecular Medicine. My education, training, and experience are further set forth in my Curriculum Vitae (CV), which is attached to this report as **Exhibit A**.

As detailed in my CV, my research activities have examined a number of basic questions in human cancer such as the role of viral infection in head and neck cancer, the role of genetic mutation in risk for secondary cancer events following initial treatment, the genetics of B-cell

lymphoma, hepatosplenic T-cell lymphoma and malignant melanoma, and the role of STAT3 in triple-negative breast cancer. As the founding and Executive Director of the HudsonAlpha Clinical Services Laboratory, I also have interests and responsibilities in the clinical use of genetic testing for cancer risk and treatment stratification. HudsonAlpha launched the Information is Power campaign and has provided genetic testing for breast and ovarian cancer risk to women across the state of Alabama free of charge. My lab has also supported the Alabama Genomics Health Initiative that tests for genetic risks and carrier status for a number of diseases, including breast and ovarian cancer. This body of work in basic and clinical research in combination with earlier epidemiological work in the Shanghai Women's Health study provides the experience, education and expertise to develop this report.

I have been retained to describe the role of genetics in the pathogenesis of cancer in general and specifically ovarian cancer. Further, I have been asked to assess whether perineal use of talcum powder products induces a biologically plausible mechanism or mechanisms that result in ovarian cancer.

My report consists of a review and my conclusions regarding this cause-and-effect relationship. My opinions are based on my assessing and weighing the totality of the evidence, including relevant literature and available documentation, and my experience as a geneticist and scientific researcher. Report references are listed at the end of this report, and a more comprehensive list of the documents and materials reviewed prior to formulating the opinion in this report is attached as **Exhibit B**. The methodology that I have used to reach my opinions in this case is generally accepted in the scientific community and is the same methodology that I use in my research and other professional activities. All of my opinions stated below are held to a reasonable degree of scientific certainty. My opinions reflect my sole and independent judgment at the time of this report.

My billing rate is \$500 per hour. I have not testified by deposition or at trial during the last four years.

II. Cancer Overview

Cancer has become a descriptor that is ubiquitously used but describes an extremely complex and diverse collection of medical conditions. Cancer is also a word that represents an amazingly complicated and often misunderstood collection of diseases. At the most basic level, cancer can be described as a disease of unregulated cell growth but its simplicities end with that simple description. From the moment of conception until death, humans experience an unending cycle of cell growth, differentiation and death. As infants grow to children and then to adults, there are an array of growth processes that occur that represent the milestones of development and maturation. These processes are an orchestra of highly coordinated and regulated events with important checks and balances. When those highly regulated processes are defective or the checks and balances malfunction, the growth of the cells can become unregulated. Which tissue or cells become unregulated and exactly what process is defective defines the type of cancer and its progression. Cancer can be aggressive and highly metastatic when unregulated cells invade other parts of the body and destroy organs and tissues. Other types of cancer remain restricted to specific organs or cell types and may be less aggressive.

It is the DNA within our cells which provides the genetic code or instructions to create the cells, tissues, and organs that make a human. Subtle changes in that code lead to the diversity of people around the world, while more substantial changes in that code create the diversity of life forms around us, from the smallest bacteria to the largest plants and animals. All cells have one set of instructions that provides the information for cells to divide, tissues to grow and how cells should die.

III. The Role of Gene Mutations in the Development of Cancer

At its fundamental level, cancer is caused by changes (mutations) to the DNA within cells. The DNA that makes up our genetic code is organized into a large number of individual genes, each of which contains a specific subset of instructions telling the cell what functions to perform, as well as how to grow and divide. Errors in the instructions can cause the cell to stop its normal function and may allow a cell to become cancerous. Mutations that cause cancer most commonly

disrupt the regulation of the cell cycle (i.e., stages of cell growth and division). The following classifications of mutations are those most commonly found in cancer, but many other gene mutations can contribute to causing cancer as well.

Increasing cell growth and division. A gene mutation can initiate more rapid cell growth and division, resulting in many new cells that all have that same mutation. Proto-oncogenes are a group of genes that regulate cell growth, differentiation, division and death. When a proto-oncogene is mutated, it can become an oncogene that then instructs the cell to grow rapidly in an unregulated manner.

Loss of growth inhibition. A gene mutation can result in the renewed growth of a cell that had previously stopped growing. Normal cells regulate their division so that the human body contains the appropriate number of each type of cell. When the tumor suppressor genes that provide this inhibitory control become mutated, cells become cancer cells and continue to grow and amass. An example of one such gene is *p53*, which is discussed in more detail below.

Loss of DNA repair. Gene mutations can also affect the genes that proofread DNA and fix mutations before they can have a detrimental effect. DNA repair genes look for errors in a cell's DNA and make corrections. A mutation in a DNA repair gene may mean that other errors aren't corrected, leading cells to become cancerous through unchecked replication of damaged cells. Examples of DNA repair genes include *BRCA1* and *BRCA2* which are discussed in more detail below.

Another way of classifying gene mutations is by when they occur.

- 1) Inherited gene mutations: Inherited gene mutations are those mutations an individual is born with and that are present in all cells of the body. These types of mutations define traits and characteristics that have a family history. This type of mutation directly accounts for a small percentage of cancers. The indirect effects of this type of mutation is an area of active research. There are a growing number of genes and mutations that are known to increase the risk of cancer. *BRCA1* and *BRCA2* mutations and the increased risk for breast and ovarian cancer are two examples. While additional genes are being identified, the

percentage of individuals affected by mutations in those genes will be significantly less than those affected by *BRCA1* and *BRCA2*.

- 2) Acquired (somatic) gene mutations: Somatic mutations are acquired after birth. Most gene mutations that directly cause cancer occur after birth and aren't inherited. Gene mutations can be caused by a number of events or exposures. These include environmental exposures such as smoking, radiation, and cancer-causing chemicals (carcinogens). Biological and lifestyle exposures such as viruses, obesity, hormones, and chronic inflammation are also known to result in cancer-causing mutations. Each exposure type has its own mechanism in increasing risk for cancer. These mechanisms may be direct, such as radiation directly damaging DNA, as well as indirect, such as an external agent causing a cellular reaction or inflammatory response that then leads to DNA damage or mutation.

Both inherited and acquired gene mutations work together to cause cancer. While genetic testing has become commonplace for both assessing risk for cancer as well as directing treatment, the catalog of oncogenes, tumor suppressor genes, and DNA repair genes make genetic testing valuable and impactful for informing patients of their genetic risk for cancer. Genetic testing generally detects inherited mutations. Currently, genetic screening does not detect acquired gene mutations because they occur only in certain cells. Even if one has inherited a genetic mutation that predisposes one to cancer, that doesn't mean he or she is certain to get cancer. Rather, one or more additional gene mutations may be needed to cause cancer. The inherited gene mutation could instead make one more likely to develop cancer when exposed to a certain cancer-causing substance. Conversely, an individual may still develop cancer if they do not have mutations known to predispose one to cancer. Additionally, chemical and other environmental agents such as talcum powder products can interact with inherited mutations to cause ovarian cancer.

IV. The Role of Genetics in Ovarian Cancer

Ovarian cancer is the major cause of death from gynecologic disease and the second most common gynecologic malignancy worldwide (Nunes and Serpa, 2018; Siegel, 2015; Torre, 2015). The term "ovarian cancer" is often used to include fallopian tubal, ovarian epithelial and peritoneal

cancers since the pathogenesis, treatment and clinical courses are similar. Researchers now believe that most of these cancers originate in the distal portion of the fallopian tube (Levanon, 2008). The significant mortality is primarily associated with late diagnosis and resistance to therapy (Bowtell, 2010). Epithelial ovarian cancer (EOC) includes most malignant ovarian neoplasms (Chan, 2006) that can be classified based on morphologic and molecular genetic features into the following types: serous (OSC; low and high grade), endometrioid (EC), clear cell (OCCC) and mucinous (MC) carcinomas.

Certain specific genetic and transcriptional signatures are associated with each histological subtype. Low-grade OSC cases generally have genetic alterations in BRAF, KRAS, NRAS, and Erb-B2 Receptor Tyrosine Kinase 2 (ERBB2); high-grade OSC has mutations in Tumor Protein P53 (TP53), BRCA1/2, Neurofibromin 1 (NF1), RB Transcriptional Corepressor 1 (RB1), and Cyclin Dependent Kinase 12 (CDK12) (Chan, 2006). Homologous recombination repair of DNA damage is defective in approximately 50% of high-grade serous cancers along with alterations in signaling pathways such as PI3/Ras/Notch/ FoxM1 (Nunes and Serpa, 2018).

Endometrioid carcinoma (EC) subtypes involve mutations in AT-Rich Interaction Domain 1A (ARID1A), Phosphatidylinositol-4,5-Bisphosphate 3-Kinase Catalytic Subunit Alpha (PI3KCA), Phosphatase And Tensin Homolog (PTEN), Protein Phosphatase 2 Scaffold Subunit Alpha (PPP2R1 α), and mismatch repair deficiency. Ovarian clear cell carcinoma (OCCC) subtypes have been found with de novo expression of HNF1 β (Mabuchi, 2009; Shen, 2013) as well as ARID1A, PI3KCA, PTEN, Catenin Beta 1 (CTNNB1) and PPP2R1 α mutations. MC comprises tumors with mutations in KRAS and a high frequency of ERBB2 amplification with overexpression of mucin-coding genes (Banerjee and Kaye, 2013; Jayson, 2014).

In addition to inherited mutations, exposure to the environment can result in DNA changes, or acquired gene mutations, that lead to cancer. These sources can be from exposure to minerals such as asbestos or arsenic, chemical exposures such as benzene or formaldehyde and from natural radiation sources like radon or ultraviolet light. These exposures constantly damage human DNA. Fortunately, cells have robust DNA repair mechanisms to ensure DNA damage is repaired before the DNA is replicated. These “proofreading” mechanisms react to DNA damage and stop DNA

replication. The mechanisms involve checkpoint control proteins such as the p53 protein, which acts to stop the cell cycle if DNA is damaged, and thus to suppress production of tumors. Cells that do not express functional p53 protein exhibit high rates of mutation in response to DNA damage, accelerating the formation of tumors.

BRCA1 and BRCA2 proteins also function in the DNA repair pathway. *BRCA1* and *BRCA2* are normally expressed in the cells of breast and other tissue, where they help repair damaged DNA, or destroy cells if DNA cannot be repaired. They are involved in the repair of chromosomal damage resulting from double-strand breaks. *BRCA1* combines with other tumor suppressors, DNA damage sensors and signal transducers to form a large multi-subunit protein complex known as the BRCA1-associated genome surveillance complex (BASC). *BRCA2* interacts with the RAD51 protein, also forming a complex that is vital for DNA repair.

Individuals can inherit mutations in *BRCA1*, *BRCA2* or *p53*,¹ and are termed “positive” for the gene mutation. Such mutations will detrimentally affect the ability to repair DNA or sense the presence of damaged DNA. These defects allow additional mutations to accumulate in cells and lead to a higher probability of cells becoming cancerous. *BRCA1*, *BRCA2* and *p53* mutations can also be acquired in certain cells. If those cells form a tumor, the cancerous tissue can be tested for these gene mutations.

BRCA mutations are inherited in an autosomal dominant fashion, meaning inheriting only one copy results in increased cancer risk. Some individuals with a mutation in the *BRCA1* or *BRCA2* gene will develop cancer during their lifetime, but others will not. Penetrance refers to the proportion of individuals with a genetic mutation who exhibit symptoms of the disorder. Where some carriers do not develop a disorder, as in the case of *BRCA* carriers, the condition is said to have incomplete penetrance. In such instances, additional genetic, environmental and lifestyle factors must be present for the disorder to manifest. The lifetime risk for ovarian cancer is approximately 40 percent for *BRCA1* carriers and 15 to 20 percent for *BRCA2* carriers (Berek et

¹ Genes consist of genetic information that code for functional proteins. Both the gene and the protein they code share the same alphanumeric name. To avoid confusion, genes are italicized in text and proteins are not. For example: *BRCA1* (gene) and BRCA1 (protein).

al., 2012; Paluch-Shimon et al., 2016). Therefore, the presence of mutations in the *BRCA* genes do not guarantee that carriers will get cancer. The presence of these mutations increases a person's risk of developing cancer when exposed to a carcinogen (Park, 2018; Vitonis, 2011; Wu, 2015).

Mutations in *BRCA* genes are found in the minority of epithelial ovarian cancer cases, suggesting additional mechanisms involving other genes that predispose women to ovarian cancer. The location of the mutation within the *BRCA1* and *BRCA2* genes has been associated with different ovarian cancer risk (Rebbeck, 2015). Additionally, several common alleles, or alternate forms of a gene, have been found to modify ovarian cancer risk for *BRCA1* and *BRCA2* mutation carriers. These modifier genes alter the process by which information from a gene is used to synthesize a final gene product (gene expression) in another gene, which in turn causes a disease. They are hypothesized to act as low to moderate penetrance alleles that contribute to ovarian cancer risk. (Barnes and Antoniou, 2012; Ramus, 2008; Saed, 2017; Sellers, 2008). These modifiers consist of changes in the DNA called single-nucleotide variants (SNVs), and result in a point mutation in the gene. The mutation can result in a structurally altered protein that is functionally defective. Some of the affected proteins are oxidants, antioxidants, or otherwise involved in regulatory pathways involving cancer risk, as discussed below.

Lynch syndrome is another hereditary condition that increases the risk of ovarian cancer. It is caused by mutations that impair DNA mismatch repair, and the disease is inherited in an autosomal dominant manner similar to *BRCA* mutations. As in the case of *BRCA* mutations, due to incomplete penetrance inheriting a Lynch-associated mutation does not guarantee an individual will get cancer, but rather, that the risk of cancer will increase when exposed to a carcinogen.

Myriad Genetics was an early pioneer in the development of commercial genetic testing for *BRCA1* and *BRCA2* mutations and predicting risk for breast and ovarian cancer. As with all inherited traits, a positive family history is the strongest indicator of the presence of genetic risk alleles in an individual. Since the exact identity of those risk alleles and the magnitude of cancer risk remain unknown until testing is performed, early guidelines for testing were based on a positive family history. The availability of testing has increased and costs of testing have fallen. However, genetic testing remains a relatively rare practice in the general population. Since the

early 1990s, advanced molecular biological technologies have allowed for the connection to be made between specific genetic mutations and the resulting hereditary cancers. Because of the large number of individuals tested and the ability to trace their genetic inheritance, the genes involved in cancer development are well established. In the overall spectrum, there are additional variants and genes with minor involvement, but development is dependent upon specific and complex interactions that occur in rare situations, and it is extremely unlikely any would have impact of known mutations such as *BRCA1* or *BRCA2*.

V. Response to Cellular Injury

As previously mentioned, from the moment of conception, the human body relies on continuous cell growth and development for normal health and function. Some tissues and cell types continually turn over. Our skin, blood cells, immune cells and the cells that line our digestive tract are examples where cells are continually growing and replacing older cells. In the case of an injury, a complex cascade of events begins which involves inflammation and culminates in the healing of the wound. During tissue injury, cell proliferation is enhanced while the tissue regenerates. After the healing is complete, proliferation and inflammation subside.

In contrast, proliferating cells that sustain DNA damage and/or mutagenic insult (for example, initiated cells) continue to proliferate in microenvironments rich in inflammatory cells and growth/survival factors that support their growth. In a sense, tumors act as wounds that fail to heal (Dvorak, 1986). Recent studies have shown a link between inflammation associated with wound healing and ovarian cancer cell seeding (Jia, 2018). In addition to inflammation, the innate immune response plays a role in promoting cancer development and progression. These observations are generally accepted in the scientific literature (Coussens and Werb, 2002; Pardoll, 2002).

VI. Inflammation

A. The Role of Inflammation in Cancer - General

The functional relationship of cancer and inflammation was first described in the mid-1800s. Rudolf Virchow noted leucocytes in neoplastic tissues in 1863 and made a connection between inflammation and cancer (as cited in Balkwill and Mantovani, 2001). He suggested that the "lymphoreticular infiltrate" reflected the origin of cancer at sites of chronic inflammation. Research published over the last 20 years has provided further understanding of the inflammatory microenvironment of malignant tissues and validates Virchow's hypothesis. Furthermore, the links between cancer and inflammation now have quite strong implications for prevention and treatment. (Balkwill and Mantovani, 2001).

Macrophages are versatile immune-system cells that play a variety of roles in health and well-being. They act in tissues and free-floating cells in the blood that engulf and digest cellular debris, foreign substances, infectious microbes, cancer cells and anything that does not have the correct cell surface proteins to indicate a healthy cell to the body. They take various forms with various names throughout the body and have specialized tasks, including recruiting other immune cells like lymphocytes to sites of infection or acting as antigen presenting cells to T cells. Upon activation by contact with substances foreign to the body, macrophages release small proteins called cytokines. Generally speaking, macrophages can increase inflammation or decrease inflammation depending on the cytokines released.

Tumor-associated macrophages (TAM) are a major component of the infiltrate of most, if not all, tumors (Franklin and Li, 2016). TAM derive from circulating monocytic precursors, and are directed into the tumor by chemoattractant cytokines called chemokines. Many tumor cells also produce cytokines called colony-stimulating factors that prolong survival of TAM. When appropriately activated, TAM can kill tumor cells or elicit tissue destructive reactions on the vascular endothelium to disrupt blood supply to the tumor. However, TAM also produce growth and angiogenic factors as well as protease enzymes which degrade the extracellular matrix. Therefore, TAM can stimulate tumor-cell proliferation, promote angiogenesis, and favor invasion and metastasis (Mantovani, 1992b; Mantovani, 1997). Direct evidence for the importance of

protease production by TAM, neutrophils, and mast cells during experimental carcinogenesis was reported more than 15 years ago (Coussens, 2000). Since that time, the report by Coussens et al has been cited nearly 300 times by other studies. This dual potential of TAM has been described in the literature as the "macrophage balance." (Liu and Cao, 2015; Mantovani, 1992a).

B. The Role of Inflammation in Ovarian Cancer

Inflammation has also been shown to play a key role directly in epithelial ovarian cancer. This principle is generally accepted in the scientific community and very well reviewed in the scientific literature over the last decade, as the role of inflammation is common in many types of cancer. (Charbonneau, 2013; Kisielewski, 2013; Maccio and Madeddu, 2012; Mor, 2011; Pardoll, 2002; Pejovic and Nezhat, 2011; Shan and Liu, 2009). The literature reviews, as well as many direct studies, feature the immune system as being an important mediator of ovarian carcinogenesis via two models for its role in ovarian cancer: 1) chronic inflammation and 2) incessant ovulation.

- 1) Chronic Inflammation: The chronic inflammation model of carcinogenesis proposes that chronic exposures to external or endogenous triggers of immunity (such as known carcinogens) and the persistence of immune cells cause ovarian cancer. These inflammatory triggers cause injury to surrounding epithelium, damage DNA through the release of reactive oxygen species (ROS), or produce cytokines that promote proliferation (Saed, 2017). One environmental exposure shown to induce inflammation in animal models and human lungs is talcum powder (Wehner, 1994). Composed primarily of magnesium silicate, talc has been linked to ovarian cancer risk in a number of studies (Ness, 2000; Mills, 2004; Merritt, 2008; Wu, 2009; Rosenblatt, 2011; Wu, 2015; Penninkilampi, 2018).
- 2) Incessant Ovulation: As stated in (Charbonneau, 2013), incessant ovulation results in damage due to rupturing of the ovulating follicle, which traumatizes the ovarian surface causing an immediate inflammatory response and wound repair. Repeating this process of damage and epithelial proliferation to repair the wound increases the risk of malignant transformation. Epidemiologic studies beginning nearly 50 years ago have implicated increased number of ovulations as a risk factor for ovarian cancer (Mahdavi, 2006). In

contrast, decreased risk of (i.e., protection from) ovarian cancer has been associated with increased parity (Adami, 1994; Modan, 2001), oral contraceptive use (Narod, 1998), breast feeding (Jordan, 2012) and older age at first menses (Titus-Ernstoff, 2001). All of these protective factors impact the number of lifetime ovulations. One of these early studies from the late 1970's, which has been further substantiated by more recent investigations, found protective effects of "anovulatory time" by combining information on both increased oral contraceptive use and parity as well as age at first and last menses (Casagrande, 1979), supporting the theory of incessant ovulation as an underlying mechanism of carcinogenesis.

As a part of the inflammatory response, macrophages induce oxidative stress through production of reactive oxygen species (ROS) and reactive nitrogen species (RNS). Normally, oxidants and antioxidants maintain a balance wherein the amount of ROS does not overwhelm the ability of the body, and antioxidants, to regulate them. Free radicals such as ROS and RNS are highly reactive and adversely alter DNA, proteins, and lipids (which comprise cell membranes) to promote tumor development and progression, and many cancers arise from sites that are subject to chronic irritation, infection, or inflammation. Cancer cells persist in a pro-oxidant state where there is excess production and generation of ROS that allows for tumor initiation, promotion and progression.

The association between exposure to pathogens and chronic inflammation in tumor promotion and progression is further support of the generally understood principle that chronic inflammation plays a key role in the development of ovarian cancer. Examples of inflammatory conditions that are associated with ovarian cancer include endometriosis and pelvic inflammatory disease. Evidence strongly suggests that endometriosis is a pelvic inflammatory condition (Agic, 2006), and that inflammation explains the association between endometriosis and epithelial ovarian cancer (Ness, 2000). Studies have found a relationship between pelvic inflammatory disease and ovarian cancer risk (Lin, 2011; Merritt, 2008). Moreover, the effect of non-steroidal anti-inflammatory drugs (NSAIDs) to reduce the risk of ovarian cancer provides additional support. The earlier studies with a focus on NSAIDs were preliminary and results were somewhat

inconsistent (Bonovas, 2005; Merritt, 2008), but a recent pooled analysis examining 12 case-control studies found aspirin could reduce ovarian cancer risk by 20%-34% (Trabert, 2014).

Additional studies illustrate the potential protective effects of anti-inflammatory agents, including from unexpected drugs such as metformin. As reviewed in Reid, 2017, evidence supports a role for the anti-diabetic agent, metformin, in the prevention and treatment of multiple cancers (Li, 2011). Studies reviewed include a case-control study including 1,611 incident ovarian cancer cases performed using the UK-based General Practice Research Database (Bodmer, 2011). Long-term use (≥ 30 prescriptions) of metformin (and not sulfonylureas or insulin) was associated with a trend towards reduced risk with an odds ratio of 0.61. Though these results alone were not statistically significant, the reported observation that the anti-inflammatory agent, metformin, appears to decrease the risk of cancer, is additional evidence that inflammation is a primary mediator of ovarian cancer. (Irie, 2016).

Considering the well-established role that inflammation plays in cancer and the beneficial effects of anti-inflammatory compounds on cancer risk and progression, it is logical to examine the environmental factors that may directly lead to cancer or that may increase chronic inflammation and indirectly lead to cancer. The International Agency for Research on Cancer (IARC) has recognized for nearly thirty years that there is sufficient evidence to conclude human exposure to asbestos is a cause of ovarian cancer (IARC, 1987; IARC, 2012). Not surprisingly, human studies have reported asbestos fibers in ovaries (Heller, 1996; Langseth, 2007). Meta-analysis continues to support the conclusion that exposure to asbestos increases risk for ovarian cancer (Camargo et al., 2011).

C. Talcum Powder Products

A number of studies have been performed to examine the role of talcum powder use in the development of ovarian cancers. A comprehensive and recent meta-analysis by Penninkilampi found an association between perineal talc use and ovarian cancer, with a greater association after a higher number of lifetime applications (Penninkilampi and Eslick, 2017). The Penninkilampi study identified 24 case-control (13,421 cases) and three cohort studies (890 cases). Observational studies involving at least 50 cases of ovarian cancer were eligible for inclusion. Penninkilampi

analyzed the association between ovarian cancer and any perineal talc use. Included studies reported specific types of ovarian cancer, long-term (>10 year) talc use total lifetime applications, frequency and use of talc while also using diaphragms or sanitary napkins.

The Penninkilampi study found a consistent association between perineal talc use and ovarian cancer. Variation in the magnitude of the effect was found when considering study design and ovarian cancer subtype. Any perineal talc use was associated with increased risk of ovarian cancer (OR=1.31, 95%CI 1.24-1.39). Greater than 3,600 lifetime applications (OR=1.42, 95%CI 1.25-1.61) was slightly more associated with ovarian cancer than less than 3,600 applications (OR=1.32, 95%CI 1.15- 1.50).

In addition to epidemiological evidence, an *in vitro* experiment by Buz'Zard and Lau reported an increase in ROS generation, increased cell proliferation and neoplastic transformation (conversion into cancerous cells) in human ovarian cells treated with talcum powder (Buz'Zard and Lau, 2007). They also found talcum powder treatment increased the number of reactive oxygen species produced by polymorphonuclear neutrophils, inflammatory cells whose role is to release large quantities of reactive oxygen species in response to a variety of harmful foreign stimuli. Additional studies have also shown the effects of talc on the immune response (Hamilton, 1984; Keskin, 2009; NTP, 1993).

Some studies have suggested that the link between ovarian cancer and talcum powder product use may be influenced by a number of genes (Belotte, 2015; Fletcher, 2018^a; Gates, 2008; Shukla, 2009). Gates and colleagues found that women with certain genetic variants in glutathionine S-transferase M1 (GSTM1) and/or glutathionine S-transferase T1 (GSTT1) may have a higher risk of ovarian cancer associated with talc use (Gates, 2008). In a recently peer-reviewed and accepted abstract, Harper and Saed report a mechanism by which talc enhances the pro-oxidant state in normal (ovarian and tubal) and ovarian cancer cells, through induction of gene point mutations (corresponding to known specific single nucleotide polymorphisms - SNPs) in key oxidant enzymes, altering their activities (Harper and Saed, 2018).

In a more recent study, talcum powder increased mRNA levels of pro-oxidant enzymes in normal ovarian epithelial cells and ovarian cancer cell lines, while decreasing the mRNA levels of

antioxidant enzymes (Saed et al., 2017; Saed et al., 2018). A follow-up study reported in an abstract showed epithelial ovarian cancer cells treated with talc to demonstrate increased levels of CA-125 (Fletcher, 2018^b). CA-125 is a biomarker that has been found to be elevated in patients with ovarian cancer and is currently FDA approved for disease monitoring in patients with epithelial ovarian cancer, as well as those with BRCA mutations or who are in another in high-risk group.

D. Asbestos, Fibrous Talc, Heavy Metals and Fragrance Chemicals

In addition to the mineral talc, I have seen evidence that talcum powder products, including Johnson's Baby Powder and Shower to Shower, contain asbestos², and heavy metals³ such as chromium, cobalt, and nickel. A 2017 study by Longo and Rigler on historic samples of Johnson & Johnson baby powder ranging in production date over a span of many years showed over one-half (17 of 30) of Johnson's talcum powder product samples contained asbestos (Longo and Rigler, 2017). Talc containing asbestiform fibers (fibrous talc) was found in 15 of the 30 samples. A 2018 study by Longo and Rigler reported the presence of fibrous anthophyllite in products tested from 1978 as well as fibrous talc in both (Longo and Rigler, 2018). Additionally, I have reviewed the expert report of Drs. Longo and Rigler reporting that 37 of 56 historical talcum powder samples contained asbestos and 41 of the 42 samples tested contained fibrous talc⁴.

Asbestos has long been recognized as a well-known carcinogen and exposure can cause lung disease, mesothelioma, and cancers of the lung, larynx, and ovary (IARC 1987, 2012). It is established that asbestos exposure can result in macrophage activation, inflammation, generation of reactive oxygen and reactive nitrogen species, tissue injury, genotoxicity, and resistance to programmed cell death (Aust, 2011; Hein, 2007; IARC, 2012; Jaurand, 1997; Wang, 1987). One of the direct mechanisms is through interactions between internalized fibers and components of mitosis, resulting in chromosomal alterations and abnormalities (Hesterberg et al., 1986; Wang et al., 1987; Yegles et al., 1993). IARC has classified asbestos as a known human carcinogen (Group

² Ex. 28, Hopkins Dep. (Aug. 16 & 17, 2018; Oct. 17, 2018; and Nov. 5, 2018); Blount, 1991; Paoletti, 1984.

³ Ex. 47, Julie Pier Dep. (Sept. 12 & 13, 2018).

⁴ Expert Report of William E. Longo, PhD and Mark W. Rigler, PhD (Nov. 14, 2018).

1). Human tumors resulting from asbestos exposure can be characterized by genetic and chromosomal alterations that lead to the inactivation of tumor-suppressor genes (IARC, 2012).

Talc not containing asbestiform fibers has been found by IARC to be a Group 2b or “possible” carcinogen (IARC, 2010). IARC has determined that fibrous talc or talc containing asbestiform fibers (talc occurring in a fibrous habit) is a carcinogen to humans (IARC, 2012).

Chromium and nickel are classified by IARC as Group 1, “carcinogenic to humans” (IARC, 2012). Cobalt is classified as Group 2B, “possibly carcinogenic to humans” (IARC, 2006). IARC defines possibly carcinogenic as “a positive association has been observed between exposure to the agent and cancer for which a causal interpretation has been considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence.” Established carcinogenic mechanisms of chromium include DNA damage, mutation, genomic instability, and cell transformation (IARC, 2009). Similar mechanisms result from nickel exposure (IARC, 2012). Cobalt exposure has been shown to cause increased production of reactive oxygen species and other inflammatory and proliferative changes (IARC, 2006).

I also reviewed Dr. Michael Crowley’s report discussing the numerous fragrance chemicals added to talcum powder products. I am in agreement with Dr. Crowley’s opinion that these chemicals contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products. The presence of these constituents as part of talcum powder products provides additional evidence of biological plausibility for talc and ovarian cancer.⁵

Carcinogenesis is a complex and dynamic process that occurs due to a combination of mutations, both genetic and acquired, in an individual along with other processes. Mutations arising from environmental sources have an additive, and possibly multiplicative effect toward ultimately causing carcinogenesis (Park, 2018; Vitonis, 2011; Wu, 2015). The presence of asbestos, nickel, and chromium, known carcinogens, in talcum powder products provides further support for the conclusion that talcum powder causes chronic inflammation.

⁵ Expert Report of Michael Crowley, PhD (Nov. 12, 2018).

Based on these observations and lines of evidence, it is my opinion that talcum powder causes inflammation which initiates a biological response that includes oxidative stress, cell proliferation, inhibition of apoptosis, and genetic mutations which result in cancer development and progression. This process explains the biologically plausible mechanism for talcum powder products causing ovarian cancer.

VII. Conclusion

Based on my background, training, education, and experience as a geneticist assessing and weighing the totality of scientific evidence, my opinions may be summarized as follows:

1. Genetic mutations can be inherited or acquired. Both types are associated with cancer, including ovarian cancer.
2. Talcum powder products cause chronic inflammation.
3. Talcum powder product-induced inflammation causes damage to the DNA, genetic mutation, genomic instability, and cell transformation.
4. The properties of talcum powder products as inflammatory agents and the role of inflammation in triggering oxidative stress, activating cytokines, cell proliferation, DNA damage, and genetic mutations (such as SNVs) provide a biologically plausible mechanism for the carcinogenicity of talcum powder products.
5. Internalization of asbestiform fibers (including fibrous talc), cause DNA damage which provides a biologically plausible mechanism for the carcinogenicity of talcum powder products.
6. The presence of an inherited gene mutation, such as *BRCA1* or *BRCA2*, indicates a woman has an increased risk of ovarian cancer, but does not necessarily mean she will develop ovarian cancer.
7. Women with inherited gene mutations, such as *BRCA*, are at least as susceptible to other carcinogens as women without inherited gene mutations.

I reserve the right to supplement, revise, or amend this report should additional materials, including testimony, become available.

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Exhibit A

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fax: 256.327.9898
slevy@hudsonalpha.org

Personal Statement

My group has been utilizing high performance genotyping and sequencing technologies for the past 15 years supporting a vast diversity of projects from plant and animal phylogenetic studies to translational and clinical based projects. We have several publications detailing our successes using variety of genomic technologies as well as in the field of bioinformatics research. As a post-doctoral fellow at Emory University I developed the first microarray designed to interrogate mitochondrial gene function. Upon joining the faculty at Vanderbilt University, I was responsible for the founding and development of the Vanderbilt Microarray Shared Resource (VMSR). From 2000 to 2009, the VMSR became an internationally recognized facility supporting a wide variety of genomic technologies from SNP profiling to gene expression analysis to next-generation sequencing. I joined the faculty of the HudsonAlpha Institute for Biotechnology in 2009 to develop the Genomic Services Laboratory (GSL). Since 2009 the GSL has supported more than 1,000 principle investigators from around the world, allowing me to collaborate and participate in a broad range of genomics projects with a particular focus on applying a diversity of genomic methods to understand complex conditions. We have had a particular focus on childhood and adult cancer as well as rare disease and degenerative diseases. Together, these efforts have resulted in more than 140 peer-reviewed publications of which I am an author or co-author. More than 150 additional publications that have included data from our laboratory as a service provider have also been published since 2009. Many of these publications involve translational research or describe the genetic underpinnings of rare or complex human disease. The diversity of projects and investigators we have worked with over the last 15 years have provided a dynamic and amazing experience to evolve our own research and technology development efforts.

Contributions to Science

The following five sections provide highlights to areas where my work has contributed to areas of science. Example publications are provided with each section and a full bibliography is provided at the end of the CV.

1. My scientific career has been a somewhat atypical in that I have spent the last 15 years focusing on the development and application of genomic and bioinformatic technologies and methods to support scientific investigation in a number of areas. While there have been substantial areas of focus, my laboratory does not operate under a single or specific biological area or hypothesis. Instead, we examine ways to improve the resolution and quality of results to answer complex questions, regardless of biological relationship. The publications below are examples of contributions to technical projects or large consortium projects with goals in the evaluation or improvement of techniques or technologies.
 - a. Statnikov A, Aliferis, C, Tsamardinos, I, Hardin, D, and Levy, S. A comprehensive evaluation of multcategory classification methods for microarray gene expression cancer diagnosis. **Bioinformatics**, 2005. 21(5), p. 631-643. PMID:15374862.

- b. The MicroArray Quality Control Consortium. The MicroArray Quality Control (MAQC) project shows inter- and intraplatform reproducibility of gene expression measurements. **Nature Biotechnology**, 2006. 24(9), p. 1151-1161. PMID:16964229.
 - c. The ENCODE Project Consortium. An integrated encyclopedia of DNA elements in the human genome. **Nature**. 2012. 489, 57-74. PMID: 22955616 PMCID: PMC3439153
 - d. The Sequence Quality Control (SEQC) Consortium. A comprehensive assessment of RNA-seq accuracy, reproducibility and information content by the Sequence Quality Control consortium. **Nature Biotechnology**. 2014. 32 (9), 915-925. PMID:25150835; PMCID:4167418.
2. One area of early focus of my career was the development and analysis of mouse models for mitochondrial disease, including the knock out of the Adenine Nucleotide Translocase 2 (Ant2) gene leading to a more complete understanding of the permeability transition. This work also discovered methods to alter the mitochondrial DNA in stem cells and supported the first mitochondrial DNA transfers by stem cells.
- a. Levy SE, Waymire, KG, Kim, YL, MacGregor, GR, and Wallace, DC, Transfer of chloramphenicol-resistant mitochondrial DNA into the chimeric mouse. **Transgenic Research**. 1999. 8(2), p. 137-145. PMID:10481313.
 - b. Sligh JE, Levy SE, Waymire KG, Allard P, Dillehay DL, Nusinowitz S, Heckenlively JR, MacGregor GR, and Wallace DC. Maternal germ-line transmission of mutant mtDNAs from embryonic stem cell-derived chimeric mice. **Proc. of the Nat. Acad. of Sciences USA**. 2000. 97(26), p. 14461-14466. PMID:11106380; PMCID:18941.
 - c. Kokoszka JE, Waymire, KG, Levy, SE, Sligh, JE, Cal, JY, Jones, DP, MacGregor, GR, and Wallace, DC, The ADP/ATP translocator is not essential for the mitochondrial permeability transition pore. **Nature**, 2004. 427(6973),p. 461-465. PMID:14749836.
 - d. Picard M, Zhang J, Hanecock S, Derbeneva O, Golhar R, Golik P, O'Hearn S, Levy SE, Potluri P, Lvova M, Davila A, Lin CS, Perin JC, Rappaport EF, Hakonarson H, Trounce I, Procaccio V, and Wallace DC. Progressive increase in mtDNA 3243A>G heteroplasmy results in abrupt transcriptional remodeling. **Proc. of the Nat. Acad. of Sciences USA**. 2014. 111(38), E4033-E4042. PMID:25192935; PMCID:4183335.
3. A long-standing area of research interest is the genomic analysis of cancer, both childhood and adult. These efforts have included population-based studies and more directed research in specific cancer biology. These efforts have examined many cancer types including breast, lung, colon, and myeloid cancer.
- a. Smith JJ, Deane, NG, Wu, F, Merchant, NB, Zhang, B, Jiang, A, Lu, P, Johnson, JC, Schmidt, C, Edwards, CM, Eschrich, S, Kis, C, Levy, S, Washington, MK, Heslin, MJ, Coffey, RJ, Yeatman, TJ, Shyr, Y, and Beauchamp, RD, Experimentally Derived Metastasis Gene Expression Profile Predicts Recurrence and Death in Patients With Colon Cancer. **Gastroenterology**, 2009. PMID: 19914252 PMCID: PMC3388775.
 - b. Powell AE, Wang Y, Li Y, Poulin EJ, Means AL, Washington MK, Higginbotham JN, Juchheim A, Prasad N, Levy SE, Guo Y, Shyr Y, Aronow BJ, Haigis KM, Franklin JL, and Coffey RJ. Lrig1, a pan-ErbB negative regulator, marks intestinal stem cells and acts as a tumor suppressor. **Cell**. 2012. 149(1), 146-158. PMID: 22464327 PMCID: PMC3563328.
 - c. McDaniel JM, Varley KE, Gertz J, Savic DS, Roberts BS, Bailey SK, Shevde LA, Ramaker RC, Lasseigne BN, Kirby MK, Newberry KM, Partridge EC, Jones AL, Boone B, Levy SE, Oliver PG, Sexton KC, Grizzle WE, Forero A, Buchsbaum DJ, Cooper SJ, Myers RM. Genomic regulation of invasion by STAT3 in triple negative breast cancer. **Oncotarget**. 2017;8(5):8226-38. doi: 10.18632/oncotarget.14153. PubMed PMID: 28030809; PMCID: PMC5352396.

- d. McKinney M, Moffitt AB, Gaulard P, Travert M, De Leval L, Nicolae A, Raffeld M, Jaffe ES, Pittaluga S, Xi L, Heavican T, Iqbal J, Belhadj K, Delfau-Larue MH, Fatacciolli V, Czader MB, Lossos IS, Chapman-Fredricks JR, Richards KL, Fedoriw Y, Ondrejka SL, Hsi ED, Low L, Weisenburger D, Chan WC, Mehta-Shah N, Horwitz S, Bernal-Mizrachi L, Flowers CR, Beaven AW, Parihar M, Baseggio L, Parrens M, Moreau A, Sujobert P, Pilichowska M, Evens AM, Chadburn A, Au-Yeung RK, Srivastava G, Choi WW, Goodlad JR, Aurer I, Basic-Kinda S, Gascoyne RD, Davis NS, Li G, Zhang J, Rajagopalan D, Reddy A, Love C, Levy S, Zhuang Y, Datta J, Dunson DB, Dave SS. The Genetic Basis of Hepatosplenic T-cell Lymphoma. **Cancer Discov**. 2017;7(4):369-79. doi: 10.1158/2159-8290.CD-16-0330. PubMed PMID: 28122867; PMCID: PMC5402251.
4. My laboratory has had the opportunity to collaborate with a number of outstanding investigators in the genetics analysis of complex neurological conditions, including autism, schizophrenia and bipolar disorders as well as ALS. We contributed significantly to the discovery of the association of de-novo rather than Mendelian mutations in these conditions, particularly in schizophrenia.
 - a. Xu B, Roos JL, Dexheimer P, Boone B, Plummer B, Levy S, Gogos JA, Karayiorgou M. Exome sequencing supports a de novo mutational paradigm for schizophrenia. **Nature Genetics**. 2011. 43(9), 864-868. PMID: 21822266. PMCID: PMC3196550.
 - b. Neale BM, Kou Y, Liu L, Ma'ayan A, Samocha KE, Sabo A, Lin CF, Stevens C, Wang LS, Makarov V, Polak P, Yoon S, Maguire J, Crawford EL, Campbell NG, Geller ET, Valladares O, Shafer C, Liu H, Zhao T, Cai G, Lihm J, Dannenfelser R, Jabado O, Peralta Z, Nagaswamy U, Reid JG, Newsham I, Wu Y, Lewis L, Han Y, Muzny D, Voight BF, Lim E, Rossin E, Kirby A, Flannick J, Fromer M, Shakir K, Fennell T, Garimella K, Boyko C, Gabriel S, dePristo M, Wimbish JR, Boone BE, Levy SE, Betancur C, Sunyaev S, Boerwinkle E, Buxbaum JD, Cook EH, Devlin B, Gibbs R, Roeder K, Schellenberg GD, Sutcliffe JS, and Daly MJ. Patterns and rates of exonic de novo mutations in autism spectrum disorders. **Nature**. 2012. 485(7397), 242-245. PMID: 22495311 PMCID:PMC3613847.
 - c. Xu B, Ionita-Laza I, Roos JL, Boone B, Woodrick S, Sun Y, Levy S, Gogos JA, and Karayiorgou M. De novo gene mutations highlight patterns of genetic and neural complexity in schizophrenia. **Nature Genetics**. 2012. 44(12), 1365-1369. PMID: 23042115 PMCID: PMC3556813.
 - d. Cirulli, ET, Lasseigne, BN, Petrovski, S, Sapp, PC, Dion, PA, Leblond, CS, Couthouis, J, Lu, Y-F, Wang, Q, Krueger, BJ, Ren, Z, Keebler, J, Han, Y, Levy, SE, Boone, BE, Wimbish, JR, Waite, LL, Jones, AL, Carulli, JP, Day-Williams, AG, Staropoli, JF, Xin, WW, Chesi, A, Raphael, AR, McKenna-Yasek, D, Cady, J, Vianney de Jong, JMB, Kenna, KP, Smith, BN, Topp, S, Miller, J, Gkazi, A, Consortium, FS, Al-Chalabi, A, van den Berg, LH, Veldink, J, Silani, V, Ticozzi, N, Shaw, CE, Baloh, RH, Appel, S, Simpson, E, Lagier-Tourenne, C, Pulst, SM, Gibson, S, Trojanowski, JQ, Elman, L, McCluskey, L, Grossman, M, Shneider, NA, Chung, WK, Ravits, JM, Glass, JD, Sims, KB, Van Deerlin, VM, Maniatis, T, Hayes, SD, Ordureau, A, Swarup, S, Landers, J, Baas, F, Allen, AS, Bedlack, RS, Harper, JW, Gitler, AD, Rouleau, GA, Brown, R, Harms, MB, Cooper, GM, Harris, T, Myers, RM, Goldstein, DB. Exome sequencing in amyotrophic lateral sclerosis identifies risk genes and pathways. **Science**. 2015. Feb 19. pii: aaa3650. [Epub ahead of print] PubMed PMID: 25700176.
 5. My laboratory has played a significant role in the discovery of the causative mutations of a number of rare but significant human diseases, particularly in the field of pediatric nephrology in collaboration with Friedhelm Hildebrandt at Harvard University. These studies applied genomic technologies to better characterize and in some cases diagnose or discover the causative mutation for severe phenotypes or disease.
 - a. Otto EA, Hurd TW, Airik R, Chaki M, Zhou W, Stoetzel C, Patil SB, Levy S, Ghosh AK, Murga-Zamalloa CA, van Reeuwijk J, Letteboer SJF, Sang L, Giles RH, Liu Q, Coene KLM, Estrada-

- Cuzcano A, Collin RWJ, McLaughlin HM, Held S, Kasanuki JM, Ramaswami G, Conte J, Lopez I, Washburn J, MacDonald J, Hu, J, Yamashita Y, Maher ER, Guay-Woodford L, Neumann HPH, Obermuller H, Koenekoop RK, Bergmann C, Bei X, Lewis RA, Katsanis N, Lopes V, Williams DS, Lyons RH, Dang CV, Brito DA, Dias MB, Zhang X, Nurnberg G, Nurnberg P, Pierce E, Jackson P, Antignac C, Saunier S, Roepman R, Dollfus H, Khanna H, and Hildebrandt F. Candidate exome capture identifies mutation of SDCCAG8 as the cause of a retinal-renal ciliopathy. **Nature Genetics**. 2010. 42(10), 840-850 PMID: 20835237 PMCID: PMC2947620.
- b. Rademakers R, Baker M, Nicholson AM, Rutherford NJ, Finch N, Soto-Ortolaza A, Lash J, Wider C, Wojtas A, DeJesus-Hernandez M, Adamson J, Kouri N, Sundal C, Shuster EA, Aasly J, MacKenzie J, Roeber S, Kretzschmar HA, Boeve BF, Knopman DS, Petersen RC, Cairns NJ, Ghetti B, Spina S, Garbern J, Tselis AC, Uitti R, Das P, Van Gerpen JA, Meschia JF, Levy S, Broderick DF, Graff-Radford N, Ross OA, Miller BB, Swerdlow RH, Dickson DW, Wszolek ZK. Mutations in the colony stimulating factor 1 receptor (CSF1R) cause hereditary diffuse leukoencephalopathy with spheroids. **Nature Genetics**. 2011. 44(2), 200-205. PMID: 22197934 PMCID: PMC3267847.
- c. Fiskerstrand T, Arshad N, Haukanes BI, Tronstad RR, Pham KDC, Johansson S, Håvik B, Tønder SL, Levy SE, Brackman D, Boman H, Biswas KH, Apold J, Hovdenak N, Visweswariah SS, and Knappskog PM. Familial Diarrhea Syndrome Caused by an Activating GUCY2C Mutation. **New England Journal of Medicine**. 2012. 366(17), 1586-1595. PMID: 22436048.
- d. Carlson J, Scott LJ, Locke AE, Flickinger M, Levy S, Myers RM, Boehnke M, Kang HM, Li JZ, Zöllner S. Extremely rare variants reveal patterns of germline mutation rate heterogeneity in humans. **bioRxiv**. 2017:108290.
- e. Chao HT, Davids M, Burke E, Pappas JG, Rosenfeld JA, McCarty AJ, Davis T, Wolfe L, Toro C, Tifft C, Xia F, Stong N, Johnson TK, Warr CG, Undiagnosed Diseases N, Yamamoto S, Adams DR, Markello TC, Gahl WA, Bellen HJ, Wangler MF, Malicdan MC. A Syndromic Neurodevelopmental Disorder Caused by De Novo Variants in EBF3. **Am J Hum Genet**. 2017;100(1):128-37. doi: 10.1016/j.ajhg.2016.11.018. PubMed PMID: 28017372; PMCID: PMC5223093.

Education

College

University of New Hampshire: BS, 1994 (Biochemistry, Microbiology)
GPA 3.37
Honors Graduate, Dean's list.

Graduate School

Emory University: PhD, 2000, (Biochemistry)
GPA 3.75
Thesis title: "Genetic Alteration of the Mouse Mitochondrial Genome and Effects on Gene Expression."
Thesis advisor: Professor Douglas C. Wallace

Post-Graduate Training

Emory University, Douglas C. Wallace, March 2000-July 2000

Academic Appointments

Research Assistant Professor, Department of Molecular Physiology and Biophysics,
Vanderbilt University Medical Center, Nashville, TN, July 2000-June 2003

Adjunct Faculty, Graduate training program, Department of Biomedical Informatics,
Vanderbilt University Medical Center, Nashville, TN, January 2001-June 2003

Director, Vanderbilt Microarray Shared Resource, Vanderbilt University Medical Center,
Nashville, TN, July 2000-August 2009

Assistant Professor, Department of Biomedical Informatics, Vanderbilt University Medical
Center, Nashville, TN, July 2003-August 2009. (*Primary Appointment*)

Assistant Professor, Department of Molecular Physiology and Biophysics, Vanderbilt
University Medical Center, Nashville, TN, July 2003-August 2009 (*Secondary Appointment*)

Adjunct Associate Professor, Department of Biomedical Informatics, Vanderbilt University
Medical Center, Nashville, TN, August 2009-Present

Adjunct Associate Professor, Department of Epidemiology, University of Alabama-
Birmingham, Birmingham, AL October 2010-Present.

Adjunct Assistant Professor, Department of Genetics, University of Alabama-Birmingham,
Birmingham, AL October 2010-Present.

Adjunct Associate Professor, Department of Biological Sciences, University of Alabama-
Huntsville, Huntsville, AL January 2014-Present.

Faculty Investigator, HudsonAlpha Institute for Biotechnology, Huntsville, AL, August 2009-
Present

Executive Director, HudsonAlpha Clinical Services Laboratory, LLC, Huntsville, AL, December
2014-Present

Professional Organizations

American Medical Informatics Association, Co-chair, Genomics Working Group (2006-2007)
Association of Biomedical Resource Facilities
American Association for the Advancement of Science
American Association for Cancer Research
American Society for Human Genetics

Professional Activities

Intramural-University

Vision 2020 Personalized Medicine Committee-Task Force 3 (2009)

Intramural-Departmental

Department of Biomedical Informatics Academic Progress Committee (2005-2007)
Department of Biomedical Informatics Curriculum Committee (2007-2009)

Intramural-Center Affiliations

Vanderbilt-Ingram Cancer Center, Associate Member (2000-2009)
Vanderbilt Diabetes Research and Training Center, Member (2000-2009)

Vanderbilt Digestive Disease Research Center, Member (2003-2009)
Vanderbilt Institute of Chemical Biology, Member (2004-2009)

Extramural-Journal Review

- Reviewer- Arteriosclerosis, Thrombosis and Vascular Biology (2001-present)
- Reviewer-Bioinformatics (2001-present)
- Reviewer-Journal of Biological Chemistry (2002-present)
- Reviewer-Neuropsychopharmacology (2003-present)
- Reviewer-Kidney International (2003-present)
- Reviewer-Circulation Research (2003-present)
- Reviewer-Proceedings of the National Academy of Sciences (2004-present)
- Reviewer-Mitochondrion (2004-present)
- Reviewer-Molecular Nutrition and Food Research (2005-present)
- Reviewer-Pattern Recognition Letters (2006-present)
- Reviewer-PLOS-Genetics (2006-present)
- Reviewer-Physiological Genomics (2008-present)
- Reviewer-Genome Biology (2008-present)

Extramural-Editorial

- Member, Editorial Board- Journal of the American Informatics Association (2005-2007)

Extramural-Grant Study Section

- Reviewer- Alzheimer's Association (2002-present).
- NIDDK study section ZDK1 GRB-6 "Digestive Disease Research Development Centers" December 2002.
- NIDDK study section ZDK1 GRB-6 "Digestive Disease Research Development Centers" April 2004.
- NCI study section ZCA1 SRRB-C "Innovative Technologies for the Detection of Cancer" July 2004.
- NLM special study section-P41 Biomedical Informatics Resource Grants, April 2005.
- NLM special emphasis panel ZLM1 HS RO1, July 2005
- NIH CSR shared equipment study section ZRG1 GGG-T (30, 31), November 2005.
- DOD Ovarian Cancer Review Panel OC-2, August 2006
- NIH Special Emphasis Panel ZRG1 GGG-T Genomics and Genetics Shared Instrumentation, October 2006.
- NCI study section ZCA1 SRRB-U Development of Advanced Genomic Characterization Technologies, November 2006.
- NIDDK DK-06-017 "Silvio O. Conte Digestive Diseases Research Core Centers P30", June 2007.
- NIH Special Emphasis Panel ZRG1 GGG-A (30) - S10s genomics and proteomics shared instrumentation, July 2007.
- NIH Special Emphasis Panel ZRG1 GGG-B (30) - S10s genomics and proteomics shared instrumentation, September 2008.
- NIAAA Special Review Panel ZAA1-GG-01, November 2008
- NIH Special Emphasis Panel ZRG1 GGG-A (30) – Genes Genomes and Genetics instrumentation, October 2010.
- NIH Study Section 2011/05 GHD-Genetics of Health and Disease Study Section, February 2011.
- NIGRI Study Section 2012/05 ZHG1 HGR-P (M1) 1-H3 AFRICA Initiative, March 2012.

Extramural-Other Review

- Reviewer, American Association for the Advancement of Science Research Competitive Service-*Microarray Facilities for the Vermont Genetics Network*. April 2002.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Michigan Core Technology Alliance*. April 2003.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Michigan Core Technology Alliance*. April 2004.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. January 2007.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. March 2008.
- Reviewer, American Association for the Advancement of Science Research Competitive Service- *Review of Washington State Life Sciences Discovery Fund* June 2008.
- Reviewer, American Association for the Advancement of Science Research Competitive Service- *Review of Missouri Life Sciences Research Board* October 2008
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. June 2009.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. May 2010.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. September 2011.

Extramural-Advisory

- Member, Scientific Advisory Board, NuGen Technologies, Inc, San Carlos, CA, October 2003-December 2010.
- Member, Scientific Advisory Board, Genome Quebec Innovation Centre, Montreal, Quebec, 2008-2011.
- Member, Scientific Advisory Board, Genomic Explorations Inc, Memphis, TN, 2006-present.
- Member, Scientific Advisory Board, Rubicon Genomics, Ann Arbor, MI 2013-present.
- Chairman, Scientific Advisory Board, RainDance Technologies (BioRad), Billerica, MA 2015-present.

Honors and Awards

- Scholar Athlete, University of New Hampshire, 1993-1994.
- Dean's list, University of New Hampshire, 1992-1994.
- Career Development Award, SPORE in Gastrointestinal Cancer 2004-2005
- Co-Chair, Genomics Working Group of the American Medical Informatics Association 2006-2007.

Teaching Activities

Graduate School Courses as Course Director

BMIF 310-Foundations of Bioinformatics and Computational Biology, 28 lectures, Spring 2004
BMIF 311-Introduction to Systems Biology, 28 lectures, Spring 2009. *This course was a newly developed course for 2009.*

Graduate School Courses as Lecturer

MPB 322-Regulation of Gene Expression, 3 lectures, Spring 2002
MPB 322-Regulation of Gene Expression, 2 lectures, Spring 2003
MPB 322-Regulation of Gene Expression, 3 lectures, Spring 2004

IGP 301-Methodology, 1 lecture, Fall 2004
IGP 301-Methodology, 1 lecture, Fall 2005
IGP 301-Methodology, 1 lecture, Fall 2006
MIM 351-Functional Genomics and Proteomics, 2 lectures, Spring 2006
BMIF 310-Foundations of Bioinformatics and Computational Biology, 7 lectures, Fall 2007
BMIF 310-Foundations of Bioinformatics and Computational Biology, 7 lectures, Fall 2008
BMIF 310-Foundations of Bioinformatics and Computational Biology, 4 lectures, Fall 2009
BMIF 310-Foundations of Bioinformatics and Computational Biology, 4 lectures, Fall 2010
BMIF 310-Foundations of Bioinformatics and Computational Biology, 1 lecture, Fall 2011

Research Supervision

Ph.D. Thesis Committee Member

Stephen VonStetina-Vanderbilt University (2001-2005)
Laura Wilding-Vanderbilt University (2003-2007)
Alex Statnikov-Vanderbilt University (2005-2008)
Alisha Russell-Vanderbilt University (2006-2010)
Mawuli Nyaku-University of Alabama-Birmingham (2010-2014)

M.S. Thesis Committee Member

Alex Statnikov (2003-2005)
Joel Parker (2000-2002)

Student Mentorship

Shristi Shrestha, PhD student (2014-present)
Nripesh Prasad, PhD student (2010-2014)
Sidd Pratrapp MS student (2005-2007)
Current position: Director of Bioinformatics, Meharry Medical College, Nashville, TN

Fellow Mentorship

Lewis Frey, PhD (2004-2006)
Current position: Assistant Professor, Department of Biomedical Informatics, University of Utah, Salt Lake City, UT.

Patents Awarded

Multiplex spatial profiling of gene expression
US 7,569,392 B2

Research Support

ACTIVE

NIH RFA-HG-16-011 (Cooper/Barsh/Korf) 06/01/2017 – 05/31/2021 0.60 calendar months
\$2,840,944

Clinical sequencing across communities in the Deep South

This proposal outlines an important study to apply WGS to diagnose neonates with rare disorders, increase participation of individuals from underrepresented racial/ethnic groups in genomics clinical trials, provide educational materials appropriate to diverse audiences, equip non-genetics healthcare providers to return WGS results, assess the impact of WGS testing and

results, and engage a broad community to implement safer, more effective, and more equitably distributed genomic medicine.

1U24HD090744-01 (Levy/Zhang) 09/23/2016 – 06/30/2019 2.40 calendar months
NIH/NICHD \$6,212,400

Characterizing pediatric genomes through an optimized sequencing approach

Understanding the fundamental genetic changes associated with structural birth defects and childhood cancers is an important step in developing tools to allow more advanced prediction, treatment and prevention of these devastating conditions. We propose to combine the resources of two world-class centers to support researchers in their investigations of the genetics of birth defects and childhood cancers. This centralized resource will provide researchers with the tools and support necessary to advance our understanding and drive us closer to curing or preventing these diseases.

5UL1TR001417-02 (Kimberly) 08/18/2015 - 03/31/2019 0.60 calendar months
NIH/NCATS \$83,644

UAB Center for Clinical and Translational Science (CCTS)

The UAB CCTS will enhance human health by driving scientific discovery and dialogue across the bench, bedside and community continuum. The CCTS support this overall mission in a highly integrative network of relationships. Success in creating such an environment is dependent upon success in achieving five strategic priorities: 1) enhancing research infrastructure; 2) promoting investigator education, training and development; 3) accelerating discovery across the T1 interface; 4) expanding value-added partnerships; and 5) building sustainability.

HHSN2722012000231 (Creech) 09/01/2015 – 09/30/2018 0.24 calendar months
NIH/NIAID \$555,660

Influenza A/H7N9 Vaccine Administered with/without AS03 Adjuvant: Standard and Systems Biology

HudsonAlpha will receive human RNA samples from Vanderbilt University Medical Center. RNA-sequencing will be performed per specifications provided in the clinical protocol and clarified in the manual of procedures. We will perform all necessary experiments, including quality control assays. Once sequencing data are obtained, these FastQ/BAM files will be transferred to Vanderbilt University Medical Center and to the DMID Statistics and Data Coordinating Center (SDCC) for data analysis.

HHSN2722012000231 (Creech) 09/01/2015 – 09/30/2018 0.24 calendar months
NIH/NIAID \$56,630

Sub-study for DMID 10-0074

HudsonAlpha will receive human RNA samples from Vanderbilt University Medical Center. RNA-sequencing will be performed per specifications provided in the clinical protocol and clarified in the manual of procedures. We will perform all necessary experiments, including quality control assays. Once sequencing data are obtained, these FastQ/BAM files will be transferred to Vanderbilt University Medical Center and to the DMID Statistics and Data Coordinating Center (SDCC) for data analysis.

6U19CA179514-05 (Coffey) 09/01/2013 - 08/31/2018 0.24 calendar months
NIH/NCI \$39,254

Secreted RNA during CRC progression biogenesis function and clinical markers

Dr. Levy's laboratory will fully support RNA sequencing on 48-74 samples per year prepared from either total RNA or microRNA at the HudsonAlpha Institute for Biotechnology. Dr. Levy's laboratory will provide all required reagents, personnel and basic analysis support for the

proposed sequencing studies during years 1-5 of the project period.

5U01MH105653-03 (Boehnke) 09/19/2014 - 05/31/2018 0.60 calendar months
NIH/NIMH \$23,557

Whole Genome Sequencing for Schizophrenia and Bipolar Disorder in the GPC

Dr. Levy will participate in weekly conference calls and several yearly face-to-face meetings to help make this project successful. Any new improvements in sequencing technology, data analysis and data interpretation that are developed and/or applied at HudsonAlpha will be made immediately available to this project.

3P30CA013145-44S4 (Partridge) 04/01/2017 – 03/31/2018 0.60 calendar months
NIH/NCI \$113,863

Comprehensive Cancer Center Core Support Grant

Dr. Myers, President and Science Director of HudsonAlpha Institute for Biotechnology, will be part of the director's council. The director's council meets on a monthly basis to advise the director on all major decisions regarding the UAB-CCC, its organization, planning and evaluation and to approve new developmental research programs and review program leaderships. In addition, Dr. Myers will co-lead UAB-CCC's Experimental Therapeutics program. Drs. Absher and Levy will be co-leaders of the Cancer Cell Biology Program and Cancer Control & Population Sciences Program. Dr. Cooper is an Associate Scientist in Experimental Therapeutics program. They will consult investigators in study design and analysis related to genomic data.

4UM1HG007301-04 (Cooper/Myers) 06/14/2013-05/31/2018(NCE)0.60 calendar months
NIH/NHGRI \$1,536,927

Genomic Diagnosis in Children with Developmental Delay

The goal of this project is to address technological, analytical, and ethical challenges that prevent optimal use of DNA sequencing to improve treatment of diseases and life planning for patients and their families. We are applying next-generation DNA sequencing to meet the diagnostic needs of children with developmental delay, intellectual disability and related health problems.

Genomic Services Lab Director 4.80 calendar months

In addition to the projects listed above, Dr. Levy, as the Director of the Genomic Services Laboratory (GSL), is involved in the development and application of genomic and bioinformatic technologies and methods to support scientific research. These activities, along with fee-for-service projects, change often making it difficult to assign a precise percent effort to individual projects. Dr. Levy has reviewed his GSL obligations and confirms that the aggregate effort on all GSL projects at any given time does not exceed 40% (4.80 calendar months) of institutional effort.

PENDING

COMPLETED

US MED Research ACQ Activity (PI: Richard M. Myers)

9/16/10 - 8/31/15

Direct Costs for current year: \$2,150,777

Shawn E. Levy effort: 33% effort [4.0 cal. mos.]

Title: Global genomic analysis of prostate, breast and pancreatic cancer

The goals of this study are to provide an unprecedented comprehensive view of the molecular pathogenesis of prostate, breast, and pancreatic cancer, as well as the differential response to treatments in breast cancer. We will use next-generation DNA sequencing to measure mRNA, microRNA, DNA methylation, DNase hypersensitivity sites, histone modifications, and sites of transcription factor occupancy in tumors and matched non-tumor tissues for these three cancers. No budgetary or scientific overlap.

Role: Co-investigator

NIH (PIs of Collaborative R01: Richard M. Myers and Michael Boehnke)

8/30/11 - 6/30/14

Direct costs for current year for HudsonAlpha portion: \$1,855,348

Shawn E. Levy effort: 20% [2.4 cal. mos.]

Title: Whole Genome and Exome Sequencing for Bipolar Disorder

In this collaborative R01 grant, performed jointly with Dr. Michael Boehnke and colleagues at the University of Michigan, we are performing a detailed genetic analysis of bipolar disorder. We are using ultrahigh-throughput sequencing to determine the deep whole genome sequences from 1,000 individuals with bipolar disorder and 1,000 control individuals without the disorder.

NIH/NIAMS 1 R01 AR057202 (PI: Louis Bridges)

4/1/09 - 3/31/14

Direct Costs for current year for Myers/Absher portion: \$298,704

Shawn E. Levy effort: 5% effort [0.60 cal mos.]

Title: Genome Wide Association Study in African-Americans with Rheumatoid Arthritis

In this study, the Myers lab and Devin Absher and his lab at HudsonAlpha are collaborating with Dr. Lou Bridges and his colleagues at the School of Medicine at the University of Alabama in Birmingham to perform a genome-wide genetic association study of rheumatoid arthritis in African Americans. No budgetary or scientific overlap.

Role: Co-investigator

NHGRI P50 HG02568 (PI: David Kingsley)

4/19/02 - 5/31/12

Direct costs for current year: \$701,981

Shawn E. Levy effort: 10% effort [1.2 cal. mos.]

Title: Center for Vertebrate Diversity

The continuation of this Center of Excellence in Genome Science (CEGS) has broad goals to understand the genetic basis for the striking biological diversity seen in vertebrate animals. We use genetics, genomics, molecular biology and computational tools to study this problem, focusing on the three-spined stickleback fish. HudsonAlpha performs many of the genomic experiments for this project, including genomic DNA sequencing, cDNA sequencing, BAC map construction, and genotyping.

Role: Co-investigator

5 U54 HG004576-03 (Myers)

10/01/2007 – 09/30/2011

1.20 calendar

NIH/NHGRI

\$3,985,643

“Global Annotation of Regulatory Elements in the Human Genome”

This project, which is a collaboration between the Myers group at HudsonAlpha and Barbara Wold’s group at Caltech, along with contributions from Wing Wong, Arend Sidow, Serafim Batzoglou and Gavin Sherlock at Stanford, is part of the ENCODE Project, whose goals are to identify and understand the roles of all the functional elements throughout the entire human

genome. Our contributions are to identify transcription factor binding sites, assess the methylation status and measure RNAs with next-gen sequencing.

Role: Co-investigator

1 RC1 DK086594-01 (Southard-Smith)

09/30/2009 – 09/29/2011

0.60 calendar months

NIH

\$240,970

“Gene Networks in Neural Crest-derived Innervation of the Lower Urinary Tract”

The studies proposed aim to identify essential genes that control development of nerves in the lower urinary tract that regulate bladder control and sexual function. These studies are important for understanding how these nerves normally develop and for deriving technologies that will restore neural function in urogenital birth defects or after pelvic surgery. This proposal is in response to the broad Challenge grant area of Regenerative medicine and meets multiple needs for basic research in development lower urinary tract innervation.

Role: Co-investigator

5 P30 CA68485-13 (Pietenpol)

09/28/2004 - 08/31/2009

1.80 calendar months

NIH/NCI

\$3,553,801

“Cancer Center Support Grant”

As part of the Vanderbilt Ingram Cancer Center’s support grant, the goal of the Microarray Core is to provide genome-scale expression profiling technologies as well as analysis and informatics support to researchers who are members of the center.

5 P30DK058404-07 (Polk)

08/30/2007 - 05/31/2012

1.20 calendar months

NIH/NIDDK

\$727,500

“Molecular and Cellular Basis of Digestive Diseases”

As part of a center grant, the goal of the Microarray Core in the Vanderbilt Digestive Diseases Center is to provide support for the use of genome-scale expression profiling technologies to researchers involved in digestive disease-related research.

Role: Core Leader

5 P60 DK20593-31 (Powers)

06/01/2007 - 03/31/2012

0.24 calendar months

NIH/NIDDK

\$1,487,659

“Diabetes Research and Training Center”

As part of a center grant, the goal of the Microarray and Bioinformatics Core in the Diabetes Research and Training Center is to provide support for the use of genome-scale expression profiling technologies to researchers involved in DRTC-related research.

Role: Core Leader

2 R01 CA064277-10A1 (Zheng)

08/05/2008 - 05/31/2013

0.24 calendar months

NIH/NCI

\$324,917

“Shanghai Breast Cancer Study”

This proposal is aimed at the development of novel algorithms for the analysis of high-dimensionality data towards to the discovery of causal markers and mechanisms.

Role: Co-investigator

5 U24 DK58749-03 (George)

09/30/00 - 08/31/03

1.2 calendar months

NIH/NIDDK

Vanderbilt NIDDK Biotechnology Center

Purpose: The goal of this proposal was the establishment of a Biotechnology Center for the support of genomic studies of interest to investigators funded by the NIDDK. Microarray technologies and related informatics were central to the efforts.

Role: Co-investigator

VUMC Discovery Grant 540 (Levy)

01/01/02 - 12/31/03

1.2 calendar months

VUMC Internal Grant

\$50,000

Gene Expression Analysis of Colon Cancer

The goal of this proposal was the development of an integrated RNA and protein expression profile for colon cancer utilizing microarray and high-resolution protein profiling technologies. These profiles were useful in designing and developing both technological and informatic platforms for the combined analysis of protein and genetic profiles of cancer.

Role: Principle Investigator

ACS IRG-58-009-46 (Levy)

07/01/03 - 06/30/04

ACS/VICC

Simultaneous profiling of protein and RNA expression by mass spectrometry in intact tissue sections.

The goal of this proposal is to develop a novel technology platform that facilitates the simultaneous profiling of protein and RNA species in intact tissue samples while reporting spatial position. This will provide an unprecedented resolution to examine the biology of tumor samples and host-tumor interactions.

Role: Principle Investigator

1 R21 NS043581-01A1 (McDonald)

12/01/02 - 11/30/04

NIH/NINDS

Gene Discovery in a Putative Mouse Model of ADHD

In this proposal, microarray technology will be used to examine differential gene expression in the mouse model of ADHD, providing a rare opportunity to discover genes downstream of TR β activity that are able to produce all of the core symptoms and many adjunct features of ADHD.

Role: Co-investigator

1 U01 DK063587-01 (Hayward)

09/30/02 - 06/30/05

NIH/NIDDK

Genetic Markers of Transition Zone Hyperplasia

The goals of this proposal are the identification of biomarkers for prostate hyperplasia through the use of high-density microarray studies on novel models of prostate disease.

Role: Co-investigator

W81XWH-04-1-0626 (Levy S)

07/15/04-07/14/06

Department of Defense

Simultaneous profiling of protein and RNA expression by mass spectrometry in intact breast tissue sections.

The goal of this proposal is to continue the development of a novel technology platform that facilitates the simultaneous profiling of protein and RNA species in intact tissue samples while reporting spatial position. This proposal will specifically fund the optimization of this technology for the analysis of breast tissue samples.

Role: Principle Investigator

5 P01 HL6744-04 (Hawiger J)

12/01/01-11/30/06

NIH/NHLBI

Functional Genomics of Inflammation

As part of a Program Project Grant, the goal of the Microarray Core in the Functional Genomics of Inflammation program project is to provide genome-scale expression profiling technologies to researchers involved in the program.

Role: Core Leader

1 R01 DK068261-01 (Nagy T)

07/01/04-06/30/07

NIH/NIDDK (subcontract with UT)

Antipsychotic Drug-induced Weight Gain

The goal of this study is to understand the actions of antipsychotic drugs as they alter body weight. In this short subcontract with the University of Alabama, an animal model system used to study the molecular effects of selected drugs will be analyzed using genomic profiling techniques.

Role: Principal Investigator-subcontract

5 P60 DK20593-27 (Powers A)

07/20/02-03/31/07

NIH/NIDDK

Diabetes Research and Training Center-Microarray and Bioinformatics Core

As part of a center grant, the goal of the Microarray Core in the Diabetes Research and Training Center is to provide support for the use of genome-scale expression profiling technologies to researchers involved in DRTC-related research.

Role: Core Leader

5 P50 CA95103-04 (Coffey RJ)

09/24/02-04/30/07

NIH/NCI

SPORE in GI Cancer

This study will investigate the molecular features of tumors in GI cancer and provide full support for genomic profiling projects as part of the overall SPORE program.

Role: Core Leader

U24 CA126563 (Myers)

09/28/06 – 08/31/10

NIH/NCI

"The HudsonAlpha Cancer Genome Characterization Center

We are characterizing tumors and matched non-tumor samples for copy number variations throughout the human genome as part of The Cancer Genome Atlas project, a trans-NIH initiative aimed at learning all the genetic and genomic changes associated with cancer. We use a whole-genome genotyping method to assay more than 1 million SNPs throughout the genome.

Role: Co-investigator

1 RC1 HL100016-01 (Schey)

09/30/09 – 09/29/11

NIH-ARRA Funding

“Proteome and Transcriptome Markers of Hypertension in Urine and Plasma Exosomes”

The goal of the proposed research is to develop a novel method for discovery of molecular markers of disease that circumvents existing obstacles. Through analysis of proteins and RNA found in lipid particles isolated from blood and urine, new markers of disease will be discovered that improve diagnosis, prognosis, and prediction of response to therapy; that is, improve personalized medicine. The new methodology will be applied to reveal biomarkers of salt-sensitivity and therapeutic response in hypertensive subjects.

Role: Co-investigator

Publications

162 peer-reviewed publications with a total of 23,891 citations (as of October 2018).

A full publication and patent listing can be accessed via a public Google Scholar profile at:

<http://scholar.google.com/citations?user=xeKJAZ0AAAAJ>

As well as at NCBI:

<http://www.ncbi.nlm.nih.gov/sites/myncbi/1BODvQqGn4iAa/bibliography/43127950/public/>

Articles in refereed journals

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Exhibit B

MATERIALS AND DATA CONSIDERED

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Depositions

Deposition of Alice M. Blount in Gail Lucille Ingham, et al. v. Johnson & Johnson, et al.

Depositions of John Hopkins (Aug 16 and 17, 2018; Oct 26, 2018; Nov 5, 2018)

Deposition of Julie Pier (Sept. 12 and 13, 2018)

Expert Reports

Expert Report of Michael Crowley, PhD (Nov. 15, 2018)

Expert Report of William E. Longo, PhD and Mark W. Rigler PhD (Nov. 14, 2018)

Expert Report of William E. Longo, PhD and Mark W. Rigler PhD. Analysis of J&J Baby Powder & Valiant Shower to Shower Talc Products for Amphibole (Tremolite) Asbestos Expert Report. August 2, 2017.

Expert Report of William E. Longo, PhD and Mark W. Rigler PhD. TEM Analysis of Historical 1978 Johnson's Baby Powder Sample for Amphibole Asbestos . February 16, 2018.

Documents Produced

JNJ 000018679-90

JNJTALC000864509-732

Exhibit 16

Shawn Levy, Ph.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES,
AND PRODUCTS LIABILITY
LITIGATION

Case No. 16-2738
(FLW) (LHG)

THIS DOCUMENT RELATES TO
ALL CASES

MDL Docket No. 2738

Friday, January 11, 2019

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The video deposition of SHAWN LEVY, Ph.D.,
taken pursuant to notice, was held at the
Embassy Suites Huntsville, 850 Monroe Street
S.W., Huntsville, Alabama, commencing at
approximately 9:04 a.m., on the above date,
before Lois Anne Robinson, Registered Diplomat
Reporter, Certified Realtime Reporter, and
Notary Public for the State of Alabama.

Shawn Levy, Ph.D.

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<p>1 INDEX - (continued)</p> <p>2 Deposition Exhibit Number 15 190</p> <p>3 NTP study</p> <p>4 Deposition Exhibit Number 16 192</p> <p>5 2014 Citizens Petition to FDA</p> <p>6 Deposition Exhibit Number 17 208</p> <p>7 Buz/Zard study</p> <p>8 Deposition Exhibit Number 18 218</p> <p>9 "Perineal Talc Use and Ovarian Cancer," by Ross Penninkilampi</p> <p>10 Deposition Exhibit Number 19 249</p> <p>11 Heller article</p> <p>12 Deposition Exhibit Number 20 270</p> <p>13 Merritt paper - "Talcum Powder Chronic Pelvic Inflammation</p> <p>14 and NSAIDs in Relation to the Risk of Epithelial Ovarian</p> <p>15 Cancer"</p> <p>16 Deposition Exhibit Number 21 326</p> <p>17 Nunes article</p> <p>18 Deposition Exhibit Number 22 367</p> <p>19 Park article</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 A Good morning.</p> <p>2 Q My name is Alli Brown. I represent</p> <p>3 Johnson & Johnson, and I'll start with some</p> <p>4 questions for you here today.</p> <p>5 Dr. Levy, have you ever been deposed</p> <p>6 before?</p> <p>7 A Yes.</p> <p>8 Q And tell me, how many times?</p> <p>9 A In a setting like this, once.</p> <p>10 Q Okay. What was the nature of that</p> <p>11 deposition?</p> <p>12 A It was a patent litigation case.</p> <p>13 Q Were you serving as an expert witness</p> <p>14 in that case?</p> <p>15 A I was.</p> <p>16 Q Were you hired by the plaintiffs or the</p> <p>17 defendants?</p> <p>18 A The plaintiffs.</p> <p>19 Q And, just generally, what were the</p> <p>20 issues in that case?</p> <p>21 A It was entirely focused on evaluation</p> <p>22 of prior art in the genomic space.</p> <p>23 Q And any time --</p> <p>24 And do you remember the name of that</p>
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<p>1 VIDEOGRAPHER:</p> <p>2 We are now on the record. My name is</p> <p>3 Julie Robinson. I'm a videographer representing</p> <p>4 Golkow Litigation Services.</p> <p>5 Today's date is January 11th, 2019, and</p> <p>6 the time is 9:04 a.m.</p> <p>7 This video deposition is being held in</p> <p>8 Huntsville, Alabama, in the matter of</p> <p>9 Johnson & Johnson Talcum Powder Product Marketing,</p> <p>10 Sales Practices, and Products Liability</p> <p>11 Litigation, MDL Docket Number 2738.</p> <p>12 The deponent is Dr. Shawn Levy.</p> <p>13 Counsel will be noted on the</p> <p>14 stenographic record.</p> <p>15 The court reporter is Lois Robinson,</p> <p>16 who will now swear in the witness.</p> <p>17 SHAWN LEVY, Ph.D.,</p> <p>18 the witness, after having first been</p> <p>19 duly sworn to tell the truth, the whole truth,</p> <p>20 and nothing but the truth, was examined and</p> <p>21 testified as follows:</p> <p>22 EXAMINATION</p> <p>23 BY MS. BROWN:</p> <p>24 Q Good morning, Dr. Levy.</p>	<p>1 case, by the way?</p> <p>2 A I don't. It was, gosh, twelve years</p> <p>3 ago or so.</p> <p>4 Q I see.</p> <p>5 Did that case go to trial?</p> <p>6 A Not that I'm aware of.</p> <p>7 Q Have you ever testified at trial?</p> <p>8 A I have not.</p> <p>9 Q Okay. And other than that one patent</p> <p>10 case you just described for us, were there other</p> <p>11 depositions that you've given?</p> <p>12 A No.</p> <p>13 Q And I think, when you started to answer</p> <p>14 the question in the beginning, you said "in a</p> <p>15 setting like this." Is there another time, in</p> <p>16 your mind, where you've given testimony under</p> <p>17 oath?</p> <p>18 A No, not under oath. That's why I</p> <p>19 was --</p> <p>20 So I've had a number of meetings, all</p> <p>21 limited to the patent space of mainly prior art</p> <p>22 discussions, where there's been representatives</p> <p>23 from both sides where we were having a</p> <p>24 discussion. But it wasn't a formal deposition</p>

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<p>1 with a court reporter, under oath, et cetera.</p> <p>2 Q Understood.</p> <p>3 So this would then be the second time</p> <p>4 you've been deposed in a setting like this.</p> <p>5 A Correct.</p> <p>6 Q Is that fair?</p> <p>7 Okay. So a few ground rules that you</p> <p>8 may already be familiar with from your prior</p> <p>9 experience. First, we'll try not to speak over</p> <p>10 each other. Is that fair?</p> <p>11 A That's fair.</p> <p>12 Q That way, our court reporter can get</p> <p>13 down all my questions and all your answers.</p> <p>14 Okay?</p> <p>15 A (Nods affirmatively.)</p> <p>16 Q If you don't understand a question of</p> <p>17 mine, will you let me know?</p> <p>18 A I will.</p> <p>19 Q Okay. Try to verbalize your answers,</p> <p>20 too, so our court reporter can take them down.</p> <p>21 Okay?</p> <p>22 A Understood.</p> <p>23 Q Okay. If you need a break, let me</p> <p>24 know, and we'll be happy to accommodate you.</p>	<p>1 with.</p> <p>2 Q Okay. In front of you is the</p> <p>3 plaintiffs' lawyer's laptop. Is that right?</p> <p>4 A That's right.</p> <p>5 Q Okay. And what is contained on the</p> <p>6 plaintiffs' lawyer's laptop?</p> <p>7 MS. O'DELL:</p> <p>8 I think I'd probably be better to speak</p> <p>9 to it.</p> <p>10 MS. BROWN:</p> <p>11 No, no. Let's get it from the witness,</p> <p>12 and then if you want to make a statement for the</p> <p>13 record, of course.</p> <p>14 Q Let's -- let's get your understanding</p> <p>15 of what's on this laptop in front of you.</p> <p>16 A Other than what's on the USB drive that</p> <p>17 I've been using, I -- I don't have any knowledge</p> <p>18 of what's on it.</p> <p>19 Q Okay. Do you know what's on the USB</p> <p>20 drive?</p> <p>21 A I do.</p> <p>22 Q What's that?</p> <p>23 A It's a collection of literature cited</p> <p>24 in reliance literature list that -- from</p>
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<p>1 Do you understand you're under oath</p> <p>2 here today, same as if you were in a court of</p> <p>3 law?</p> <p>4 A I do.</p> <p>5 Q Okay. I am --</p> <p>6 And, before we get started, Doctor, I</p> <p>7 see you have a couple of items in front of you,</p> <p>8 and I want to identify what we have for the</p> <p>9 record.</p> <p>10 To your right is an iPad that is</p> <p>11 showing the realtime of my questions and your</p> <p>12 answers. Will you be using that to assist you in</p> <p>13 your testimony here today?</p> <p>14 A Yes.</p> <p>15 Q Okay. In front of you you have a</p> <p>16 laptop computer.</p> <p>17 A (Nods affirmatively.)</p> <p>18 Q Will you be using that to assist you in</p> <p>19 your testimony?</p> <p>20 A Yes.</p> <p>21 Q And tell me, is this your laptop?</p> <p>22 A It is not.</p> <p>23 Q Okay. Whose laptop is it?</p> <p>24 A The -- the attorneys I've been working</p>	<p>1 my -- from my report.</p> <p>2 Q Did you put together the items that are</p> <p>3 contained on the USB drive that you have in front</p> <p>4 of you?</p> <p>5 MS. O'DELL:</p> <p>6 Object to the form.</p> <p>7 A Yes.</p> <p>8 MS. BROWN:</p> <p>9 Q Is that your USB drive?</p> <p>10 A No. I put together the list.</p> <p>11 As far as who moved the files and</p> <p>12 organized the files on the USB, that, I don't</p> <p>13 know.</p> <p>14 Q Okay. Are all of the files on that USB</p> <p>15 drive documents that you considered in connection</p> <p>16 with your opinion in this case?</p> <p>17 A They are.</p> <p>18 Q Any other materials in front of you</p> <p>19 that you'll be using to assist you in your</p> <p>20 testimony here today?</p> <p>21 A There's a -- I have a hard copy of my</p> <p>22 report.</p> <p>23 Q Did you prepare that hard copy binder?</p> <p>24 A No.</p>

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<p>1 Q Who -- who did?</p> <p>2 A My -- the -- the attorneys I've been</p> <p>3 working with. So I -- they -- they provided the</p> <p>4 printout and the nice binder that it's in.</p> <p>5 Q Okay. Did you, Doctor, make any notes</p> <p>6 on the report that you have in front of you?</p> <p>7 A No.</p> <p>8 Q Okay. I'm gonna hand you what we have</p> <p>9 marked as Exhibit 1 to your deposition, which is</p> <p>10 a notice of your deposition.</p> <p>11 (DEPOSITION EXHIBIT NUMBER 1</p> <p>12 WAS MARKED FOR IDENTIFICATION.)</p> <p>13 MS. BROWN:</p> <p>14 Q And I'll ask, is this something that</p> <p>15 you have ever seen before?</p> <p>16 A Yes.</p> <p>17 Q When did you see it?</p> <p>18 A I'd have to review my email, but it was</p> <p>19 some -- sometime ago, some weeks ago.</p> <p>20 Q Okay. Have you brought any --</p> <p>21 And you understand that this Notice of</p> <p>22 Deposition that we've marked as Exhibit 1</p> <p>23 requests that you bring certain documents with</p> <p>24 you here today?</p>	<p>1 Thank you.</p> <p>2 -- by marking these, and I'll ask you</p> <p>3 some questions about what we have.</p> <p>4 (DEPOSITION EXHIBIT NUMBER 3</p> <p>5 WAS MARKED FOR IDENTIFICATION.)</p> <p>6 MS. BROWN:</p> <p>7 Q I'll mark as Exhibit 3 to your</p> <p>8 deposition two invoices counsel for plaintiffs</p> <p>9 just handed me, one dated May 2nd, 2018, and the</p> <p>10 other dated January 8th, 2019. And we only have</p> <p>11 one copy, so let me hand it to you and ask you,</p> <p>12 are these invoices that you created, Doctor?</p> <p>13 A They are.</p> <p>14 Q Okay. And I want to take that back for</p> <p>15 one second.</p> <p>16 Looks like the first entry on your</p> <p>17 invoice is dated May 16th, 2017. Does that sound</p> <p>18 right to you?</p> <p>19 A That sounds right.</p> <p>20 Q When were you first approached about an</p> <p>21 involvement in this case?</p> <p>22 A Earlier in 2017.</p> <p>23 Q Okay. And who approached you?</p> <p>24 A Leigh and Jennifer. I'd have to verify</p>
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<p>1 A Yes.</p> <p>2 Q Okay.</p> <p>3 MS. O'DELL:</p> <p>4 Let me just insert for the record,</p> <p>5 we've objected to certain requests contained in</p> <p>6 the notice, and objections have been served, and</p> <p>7 materials have been brought to this deposition</p> <p>8 consistent with those objections.</p> <p>9 MS. BROWN:</p> <p>10 And we are in receipt of your</p> <p>11 objections.</p> <p>12 Q And your counsel for the plaintiffs</p> <p>13 represented that some materials have been brought</p> <p>14 to the deposition. Do you have any materials</p> <p>15 with you responsive to this notice?</p> <p>16 A Well --</p> <p>17 MS. O'DELL:</p> <p>18 I'll provide to you invoices that are</p> <p>19 responsive to the Notice, and there are materials</p> <p>20 that Dr. Levy has seen since his report was</p> <p>21 served, and -- and those are copies.</p> <p>22 MS. BROWN:</p> <p>23 Thank you, counsel.</p> <p>24 Q So, Doctor, let's start --</p>	<p>1 in my email whom I may have heard from first.</p> <p>2 Q Okay. And Leigh and Jennifer are</p> <p>3 counsel for plaintiffs in this litigation; is</p> <p>4 that right?</p> <p>5 A That's right.</p> <p>6 Q And did they -- had you known them</p> <p>7 prior to receiving contact early in 2017 --</p> <p>8 A No.</p> <p>9 Q -- from plaintiffs' lawyers?</p> <p>10 A I -- I did not know them.</p> <p>11 Q Did they call you at your place of</p> <p>12 business?</p> <p>13 A I believe the first contact was email.</p> <p>14 But, ultimately, yes.</p> <p>15 Q Okay. And was there any connection,</p> <p>16 meaning did someone refer the plaintiffs' lawyers</p> <p>17 to you, or do you know?</p> <p>18 A I don't know.</p> <p>19 Q Do you have any idea how the</p> <p>20 plaintiffs' lawyers found you?</p> <p>21 A I do not.</p> <p>22 Q Okay. It looks like, Doctor, that</p> <p>23 these two invoices have a total of 33 hours.</p> <p>24 Does that sound right to you?</p>

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<p style="text-align: right;">Page 18</p> <p>1 A It does.</p> <p>2 Q Looks like something's blacked out on</p> <p>3 the second page of the invoices. Do you know</p> <p>4 what that is?</p> <p>5 MS. O'DELL:</p> <p>6 I'll just say that redactions were made</p> <p>7 by counsel. They referenced the subject matter</p> <p>8 of conversations between Dr. Levy and counsel,</p> <p>9 and those have been redacted because of work</p> <p>10 product privilege.</p> <p>11 MS. BROWN:</p> <p>12 Okay.</p> <p>13 Q Is it fair, Doctor, that you've spent a</p> <p>14 total of 33 hours forming your opinions in this</p> <p>15 case?</p> <p>16 A That's fair.</p> <p>17 Q Okay. Do you have any additional</p> <p>18 invoices that you plan to submit to the lawyers</p> <p>19 for the plaintiffs?</p> <p>20 A Yes.</p> <p>21 Q Okay. And can you ballpark for me how</p> <p>22 much additional time you've spent since the last</p> <p>23 entry here, which appears to be December 12th,</p> <p>24 2018?</p>	<p style="text-align: right;">Page 20</p> <p>1 Your report in this case was served in</p> <p>2 November of 2018; correct?</p> <p>3 A Correct.</p> <p>4 Q Fair to say, then, that Exhibit 4,</p> <p>5 which you saw for the first time in December of</p> <p>6 2018, did not inform the opinions contained in</p> <p>7 your report?</p> <p>8 A That's correct.</p> <p>9 Q Okay. Did the -- does Exhibit 4</p> <p>10 contain any information regarding chronic</p> <p>11 inflammation as the proposed mechanism of ovarian</p> <p>12 cancer induced by talc?</p> <p>13 A I don't believe it does. I'd have to</p> <p>14 review -- take a look at it to be sure.</p> <p>15 MS. O'DELL:</p> <p>16 And if you need to look at it, I'm sure</p> <p>17 counsel will hand it to you.</p> <p>18 MS. BROWN:</p> <p>19 Q I'm handing you, Doctor --</p> <p>20 MS. O'DELL:</p> <p>21 Excuse me. If you need to look at it</p> <p>22 to answer that question, you may.</p> <p>23 A To be sure I'm accurate in my answer,</p> <p>24 I'd like to take a look at that.</p>
<p style="text-align: right;">Page 19</p> <p>1 A There's probably another -- not</p> <p>2 including this morning -- roughly 15 hours.</p> <p>3 Okay. I'll hand you, Doctor, what we</p> <p>4 have marked as Exhibit 4 to your deposition.</p> <p>5 This is another document counsel for the</p> <p>6 plaintiffs just handed me.</p> <p>7 (DEPOSITION EXHIBIT NUMBER 4</p> <p>8 WAS MARKED FOR IDENTIFICATION.)</p> <p>9 MS. BROWN:</p> <p>10 Q Would you identify that for the record,</p> <p>11 please.</p> <p>12 A This is a printed copy from a website</p> <p>13 from the government of Canada discussing their</p> <p>14 draft screening assessment of talc.</p> <p>15 Q Okay. Is that something you've seen</p> <p>16 before today?</p> <p>17 A Yes.</p> <p>18 Q When did you see it first?</p> <p>19 A Sometime in December.</p> <p>20 Q Did the lawyers for plaintiffs give it</p> <p>21 to you?</p> <p>22 A They did.</p> <p>23 Q Okay. Your report in this case --</p> <p>24 Can I have that back?</p>	<p style="text-align: right;">Page 21</p> <p>1 MS. BROWN:</p> <p>2 Q Sure. Sitting here --</p> <p>3 Hold on.</p> <p>4 Sitting here today, you're not aware if</p> <p>5 Exhibit 4 contains any information regarding the</p> <p>6 proposed mechanism of chronic inflammation as a</p> <p>7 cause for ovarian cancer?</p> <p>8 MS. O'DELL:</p> <p>9 Object to the question.</p> <p>10 If you need to see the document,</p> <p>11 Doctor, you may ask for it.</p> <p>12 A Yeah. I'm not -- I'm not able to</p> <p>13 answer it accurately without seeing the document.</p> <p>14 (DEPOSITION EXHIBIT NUMBER 5</p> <p>15 WAS MARKED FOR IDENTIFICATION.)</p> <p>16 MS. BROWN:</p> <p>17 Q Okay. Handing you what we've marked as</p> <p>18 Exhibit 5, would you tell me what that is,</p> <p>19 Doctor?</p> <p>20 A This is another document from the</p> <p>21 government -- government of Canada discussing the</p> <p>22 potential risk of lung effects and ovarian cancer</p> <p>23 from talc.</p> <p>24 Q Is Exhibit 5 a final document, do you</p>

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<p>1 know?</p> <p>2 MS. O'DELL:</p> <p>3 Object to the form.</p> <p>4 A Yeah. That -- I don't -- I don't have</p> <p>5 the information available to answer that</p> <p>6 accurately.</p> <p>7 MS. BROWN:</p> <p>8 Q Have you seen Exhibit 5 prior to this</p> <p>9 morning?</p> <p>10 A I have.</p> <p>11 Q When did you first see Exhibit 5?</p> <p>12 A Similar in time to the earlier report</p> <p>13 or this -- yes. Similar in time to the</p> <p>14 earlier -- to the same document from Exhibit 4.</p> <p>15 Q To the best of your recollection,</p> <p>16 Doctor, you first saw Exhibit 5 after completing</p> <p>17 your report in this matter; is that right?</p> <p>18 A That is right.</p> <p>19 Q Fair to say, then, that Exhibit 5 did</p> <p>20 not inform the opinions contained in your MDL</p> <p>21 report?</p> <p>22 A That's correct.</p> <p>23 Q Handing you, Doctor, what we've marked</p> <p>24 as Exhibit 6 to your deposition, another document</p>	<p>1 Q Does Exhibit 6 contain any information</p> <p>2 regarding the proposed mechanism of chronic</p> <p>3 inflammation?</p> <p>4 A It does in reference, I believe. I'm</p> <p>5 reminding myself if -- if it shared the same</p> <p>6 materials that I had referenced in my report.</p> <p>7 So, yes, it does.</p> <p>8 Q Are you looking at a particular page,</p> <p>9 Doctor?</p> <p>10 A I am.</p> <p>11 Q And would you identify that for the</p> <p>12 record.</p> <p>13 A I'm looking at page 23, beginning at</p> <p>14 line 220.</p> <p>15 Q And what information does Exhibit 6 at</p> <p>16 page 23 contain regarding chronic inflammation?</p> <p>17 A It discusses inflammation of the</p> <p>18 epithelial ovarian surfaces in animal models and</p> <p>19 provides two different references.</p> <p>20 Q And were those references information</p> <p>21 you considered in forming your opinions in this</p> <p>22 case?</p> <p>23 A Let me make sure of that.</p> <p>24 Yes.</p>
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<p>1 counsel provided, counsel for plaintiffs provided</p> <p>2 in response to your deposition notice.</p> <p>3 (DEPOSITION EXHIBIT NUMBER 6</p> <p>4 WAS MARKED FOR IDENTIFICATION.)</p> <p>5 MS. BROWN:</p> <p>6 Q Would you identify for the record</p> <p>7 Exhibit 6?</p> <p>8 A So this is a draft manuscript or</p> <p>9 preprint manuscript that's been submitted for</p> <p>10 peer review discussing the systematic review and</p> <p>11 meta-analysis of the association between perineal</p> <p>12 use of talc and risk of ovarian cancer.</p> <p>13 Q Had you seen Exhibit 6 prior to this</p> <p>14 morning?</p> <p>15 A Yes.</p> <p>16 Q When did you first see Exhibit 6?</p> <p>17 A It was in December as well.</p> <p>18 Q Exhibit 6 did not inform your opinions</p> <p>19 in this matter. Fair?</p> <p>20 A They did not inform the content of the</p> <p>21 report.</p> <p>22 Q Have you reviewed and analyzed Exhibit</p> <p>23 6 since December?</p> <p>24 A I have.</p>	<p>1 Q And would you state what they are for</p> <p>2 the record, please?</p> <p>3 A One reference is T.C. Hamilton, et al.,</p> <p>4 The British Journal of Experimental Pathology,</p> <p>5 from 1984.</p> <p>6 And the other reference is "The</p> <p>7 Pathology of Ovarian" -- "The Pathology of</p> <p>8 Ovarian Cancer Precursors," which is a review of</p> <p>9 R.E. Scully in the Journal of Cellular</p> <p>10 Biochemistry, and that is a supplement from 1995.</p> <p>11 The latter is not referenced in my report.</p> <p>12 Q Have you reviewed the Scully paper in</p> <p>13 connection with your opinions in this matter?</p> <p>14 A Not specifically, no.</p> <p>15 Q You have, however, reviewed the</p> <p>16 Hamilton paper?</p> <p>17 A Yes.</p> <p>18 Q You would agree that the Hamilton paper</p> <p>19 does not show inflammation leading to neoplastic</p> <p>20 changes in animals?</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form.</p> <p>23 A I'd have to see the manu- -- or the</p> <p>24 manuscript to answer your specific question</p>

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<p>1 regarding neoplasm.</p> <p>2 MS. BROWN:</p> <p>3 Q Does the Hamilton paper support your</p> <p>4 view that chronic inflammation is a plausible</p> <p>5 mechanism for talc-induced ovarian cancer?</p> <p>6 A It supports my opinion that</p> <p>7 inflammation is a component in the progression to</p> <p>8 ovarian cancer.</p> <p>9 Q Is it your testimony that the Hamilton</p> <p>10 paper supports your opinion that chronic</p> <p>11 inflammation leads to neoplastic changes?</p> <p>12 A No, not necessarily.</p> <p>13 Q Okay. Tell me how it is that the</p> <p>14 Hamilton paper supports your opinion that chronic</p> <p>15 inflammation can cause ovarian cancer.</p> <p>16 A Well, the -- so my opinion regarding --</p> <p>17 that the role of inflammation in ovarian cancer</p> <p>18 is not based on a single study, particularly one</p> <p>19 that is now approaching or is now over 30 years</p> <p>20 old.</p> <p>21 Q Okay. Does --</p> <p>22 A So it's a -- I reviewed the -- that</p> <p>23 paper as well as a large number or the totality</p> <p>24 of the available evidence stretching across many</p>	<p>1 MS. O'DELL:</p> <p>2 -- paper in order to answer the</p> <p>3 question --</p> <p>4 MS. BROWN:</p> <p>5 Counsel --</p> <p>6 MS. O'DELL:</p> <p>7 -- you may do that.</p> <p>8 MS. BROWN:</p> <p>9 Counsel, he is absolutely entitled to</p> <p>10 get the paper. We're going to do that.</p> <p>11 Q Sitting here today, do you recall --</p> <p>12 MS. O'DELL:</p> <p>13 But he is not --</p> <p>14 MS. BROWN:</p> <p>15 It's a fair question.</p> <p>16 MS. O'DELL:</p> <p>17 Is it not a fair question.</p> <p>18 MS. BROWN:</p> <p>19 I'm not gonna --</p> <p>20 MS. O'DELL:</p> <p>21 He's asking --</p> <p>22 MS. BROWN:</p> <p>23 -- do this with you.</p> <p>24 MS. O'DELL:</p>
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<p>1 years to develop the opinion that's represented</p> <p>2 in my report.</p> <p>3 Q Sure.</p> <p>4 A And to that opinion is -- no one study</p> <p>5 or one singular piece of information is the basis</p> <p>6 of that opinion.</p> <p>7 Q Okay. But, you know, having reviewed</p> <p>8 Hamilton, that what Hamilton shows is that the</p> <p>9 inflammation they saw in the animals was not</p> <p>10 associated with neoplastic changes. Right?</p> <p>11 MS. O'DELL:</p> <p>12 Excuse me.</p> <p>13 Doctor, if you'd like to -- to pull up</p> <p>14 Hamilton, you may do that.</p> <p>15 MS. BROWN:</p> <p>16 Q And we'll certainly give you time to do</p> <p>17 that, Doctor.</p> <p>18 Sitting here today, do you recall that</p> <p>19 to be the conclusion of Hamilton?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form.</p> <p>22 You don't -- if you need to see the --</p> <p>23 MS. BROWN:</p> <p>24 Counsel --</p>	<p>1 Yes, you are. If he's asked to see the</p> <p>2 paper, he gets to look at the paper. Because</p> <p>3 this is not a situation where you can say, "Oh,</p> <p>4 I'll show it to you later," ask all these</p> <p>5 questions, try to get him to answer when he said</p> <p>6 I want to see the paper and review it. That's</p> <p>7 the way this works.</p> <p>8 MS. BROWN:</p> <p>9 Q Dr. Levy, can you answer the question</p> <p>10 without looking at the paper?</p> <p>11 MS. O'DELL:</p> <p>12 Would you repeat the question just to</p> <p>13 make sure we've got it?</p> <p>14 MS. BROWN:</p> <p>15 Yes. Would you please keep your</p> <p>16 objections to form in accordance with the federal</p> <p>17 rules?</p> <p>18 MS. O'DELL:</p> <p>19 My objections have been in accordance</p> <p>20 with the federal rules.</p> <p>21 MS. BROWN:</p> <p>22 Q Dr. Levy, my question to you was</p> <p>23 whether the Hamilton paper, the findings of the</p> <p>24 Hamilton paper show that chronic inflammation led</p>

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<p>1 to neoplastic changes. Do you recall that</p> <p>2 question?</p> <p>3 A I do recall the question.</p> <p>4 Q Can you answer that question without</p> <p>5 looking at the paper?</p> <p>6 A I would need to look at the paper to</p> <p>7 accurately answer your question.</p> <p>8 Q Absolutely. Do you have a copy on your</p> <p>9 computer?</p> <p>10 A I do.</p> <p>11 Q Okay. We'll mark it, so we're all on</p> <p>12 the same page, as Exhibit 7.</p> <p>13 (DEPOSITION EXHIBIT NUMBER 7</p> <p>14 WAS MARKED FOR IDENTIFICATION.)</p> <p>15 MS. BROWN:</p> <p>16 Q Here's a hard copy, Doctor, if that</p> <p>17 assists you.</p> <p>18 Doctor, looking at the Hamilton article</p> <p>19 that you have in front of you, does that refresh</p> <p>20 you that the authors found no association between</p> <p>21 the talc-induced changes and neoplasm?</p> <p>22 A No. Their -- their conclusions were</p> <p>23 that the talc-induced changes -- specifically</p> <p>24 fibrosis and the papillary changes -- did not</p>	<p>1 Q The Hamilton article does not support</p> <p>2 the theory that chronic inflammation leads to</p> <p>3 neoplastic changes in the ovary. Fair?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form.</p> <p>6 A The Hamilton article looked at an</p> <p>7 interval of one month, eighteen months, in a rat</p> <p>8 model. And, so, in the constraints of that</p> <p>9 particular experimental design and given the</p> <p>10 state of the art of the technology at the time,</p> <p>11 the authors did not conclude of a significant</p> <p>12 progression of ovarian cancer. But there's</p> <p>13 clearly limitations in both their experimental</p> <p>14 design and time course of the study to draw wide</p> <p>15 conclusions.</p> <p>16 MS. BROWN:</p> <p>17 Q The conclusions of the Hamilton</p> <p>18 article, Dr. Levy, do not support the hypothesis</p> <p>19 that chronic inflammation from talcum powder</p> <p>20 causes ovarian cancer. Would you agree?</p> <p>21 A I would not.</p> <p>22 Q The authors did not find that the</p> <p>23 inflammation seen in Hamilton led to neoplastic</p> <p>24 changes. True?</p>
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<p>1 appear to be a reaction to talc, but they -- I</p> <p>2 don't see the specific inclusion that you asked</p> <p>3 in the question regarding neoplasm.</p> <p>4 Q I'm looking at page 103, Doctor, the</p> <p>5 first full paragraph that begins "no evidence."</p> <p>6 You with me?</p> <p>7 A One moment. "No evidence of cellular,"</p> <p>8 that paragraph?</p> <p>9 Q Yes.</p> <p>10 And, for the record, that paragraph</p> <p>11 reads, "No evidence of cellular atypia or mitotic</p> <p>12 activity was seen in the nonpapillary areas of</p> <p>13 the surface epithelium of the injected ovaries</p> <p>14 and in no ovary was there any evidence of frank</p> <p>15 neoplasia."</p> <p>16 Correct?</p> <p>17 A It does read that way, yes.</p> <p>18 Q And that was a conclusion of the</p> <p>19 Hamilton article. Correct?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form.</p> <p>22 A That was an observation of the Hamilton</p> <p>23 article.</p> <p>24 MS. BROWN:</p>	<p>1 A The authors did not report observing</p> <p>2 neoplastic change over the time course of the</p> <p>3 given study.</p> <p>4 Q Doctor, I'm handing you the report that</p> <p>5 you've served in this case, which we'll mark as</p> <p>6 Exhibit 2.</p> <p>7 (DEPOSITION EXHIBIT NUMBER 2</p> <p>8 WAS MARKED FOR IDENTIFICATION.)</p> <p>9 MS. BROWN:</p> <p>10 Q And I'd like you to -- I'd like to</p> <p>11 direct you to page 14. I'd like to direct your</p> <p>12 attention to the last paragraph of -- the last</p> <p>13 sentence -- excuse me -- of the second full</p> <p>14 paragraph that begins "additional studies."</p> <p>15 Do you see that sentence, Doctor?</p> <p>16 A What's the beginning of that paragraph</p> <p>17 so I make sure I'm looking at the right one?</p> <p>18 Q Sure. I'd like to direct you on page</p> <p>19 14 of your report to the second full paragraph</p> <p>20 that begins "In addition to epidemiologic</p> <p>21 evidence."</p> <p>22 Do you see that?</p> <p>23 A I do.</p> <p>24 Q The last paragraph, or the last</p>

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<p style="text-align: right;">Page 34</p> <p>1 sentence of that paragraph in your report reads, 2 "Additional studies have also shown the effects 3 of talc on the immune response." 4 Do you see that sentence? 5 A I do. 6 Q And you cite the Hamilton article for 7 that proposition that we were just reviewing? 8 A Uh-huh. 9 Q True? 10 A True. 11 Q And the talc effects on the immune 12 response that were shown in Hamilton were not 13 effects that the authors observed led to 14 neoplastic changes. Correct? 15 MS. O'DELL: 16 Object to the form. 17 A I'm sorry. I'm not sure I understand 18 your question. 19 MS. BROWN: 20 Q Sure. 21 A Are you asking, if I could clarify, are 22 you -- are you asking if Hamilton is an 23 appropriate reference for the effects of talc on 24 the immune response or are you asking if</p>	<p style="text-align: right;">Page 36</p> <p>1 hypothesis that chronic inflammation leads to 2 cancer in animals. Right? 3 A The -- 4 MS. O'DELL: 5 Object to the form. 6 A The -- those two references were not 7 included in the report to provide the opinion or 8 conclusions that you just described. 9 MS. BROWN: 10 Q Because you know, Doctor, that there's 11 not a single animal study that shows that talc 12 causes changes in animals that leads to cancer; 13 right? 14 MS. O'DELL: 15 Object to the form. 16 A Could you -- could you phrase that 17 question again? Sorry. 18 MS. BROWN: 19 Q There is not a single animal study, 20 Doctor, that supports the opinion that chronic 21 inflammation caused by talc causes ovarian 22 cancer. Is that correct? 23 MS. O'DELL: 24 Object to the form.</p>
<p style="text-align: right;">Page 35</p> <p>1 Hamilton's an appropriate reference for something 2 else? 3 Q In your report, you state that studies, 4 such as Hamilton, have shown effects of talc on 5 the immune response. Correct? 6 A That is correct. 7 Q And you said Hamilton as one of the 8 articles that supports that proposition. True? 9 A Of the immune response, that's true. 10 Q Okay. The immune response that was 11 observed in Hamilton was not an immune response 12 that led to cancer. Right? 13 A As -- as I stated earlier, on the time 14 course of the Hamilton study, the authors did not 15 report specifically to neoplastic change in the 16 rat or conclude or make that conclusion, nor did 17 they conclude that that was not a possibility 18 either. 19 Q And on page 14 of your report you have 20 two additional cites for that proposition; 21 correct? 22 A Correct. 23 Q And you know, Doctor, that neither of 24 those cites, Keskin or NTP, support the</p>	<p style="text-align: right;">Page 37</p> <p>1 A In my review of the literature, there 2 are a number of animal studies that support the 3 opinions in the report regarding the biological 4 plausibility of talc leading to or contributing 5 to neoplastic change. 6 MS. BROWN: 7 Q Are you aware of any animal studies, 8 Doctor, that show talc causing chronic 9 inflammation in animals that leads to neoplastic 10 or cancerous changes in the animals? 11 MS. O'DELL: 12 Object to the form. Compound. 13 A There is one 1971 study that I'm aware 14 of. I would have to review to remember the 15 author. That was an earlier seminal -- or a 16 earlier study that described the role of talcum 17 powder and the inflammatory change within the 18 ovary. 19 MS. BROWN: 20 Q Who's the author of that study, Doctor? 21 A I'm trying to think of where I have 22 that reference. 23 Q Why don't we put that to the side and 24 at a break we'll see if we can find that article</p>

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<p>1 and then we can take a look at it. Okay?</p> <p>2 A Uh-huh.</p> <p>3 Q Okay. Getting back, then, Doctor, to</p> <p>4 what we had marked as Exhibit 6, which is the</p> <p>5 Taher paper, fair to say you reviewed that paper</p> <p>6 after your report was submitted in this case?</p> <p>7 A Yes.</p> <p>8 Q Okay. And did you notice throughout</p> <p>9 Taher's paper he makes reference to a number of</p> <p>10 supplemental materials?</p> <p>11 A Not specifically.</p> <p>12 Q Are you in receipt from plaintiffs'</p> <p>13 counsel of those supplemental materials?</p> <p>14 A I'd have to -- you'd have to give me a</p> <p>15 specific example, and I would be able to answer</p> <p>16 you.</p> <p>17 Q So, throughout the paper, the authors</p> <p>18 make reference to a set of supplemental materials</p> <p>19 that support their opinions. Do you recall that?</p> <p>20 A I certainly recall the reference</p> <p>21 materials to support their opinion. Whether they</p> <p>22 were supplemental or otherwise, that doesn't</p> <p>23 stand out to me.</p> <p>24 Q Okay. And I'm not trying to be tricky.</p>	<p>1 A And I have those on the -- available</p> <p>2 electronically.</p> <p>3 Q Okay. Were you provided with completed</p> <p>4 versions of all the plaintiff experts in the MDL</p> <p>5 proceeding?</p> <p>6 A I can't speak to whether it was all,</p> <p>7 but I have been provided with several.</p> <p>8 Q Will you list for me the expert reports</p> <p>9 you've been provided with?</p> <p>10 A Sure.</p> <p>11 Q Thank you.</p> <p>12 A There are four on -- on this drive,</p> <p>13 three -- I'm sorry. Two. Crowley and Longo.</p> <p>14 Q Two reports from Dr. Crowley and two</p> <p>15 reports from Dr. Longo?</p> <p>16 MS. O'DELL:</p> <p>17 I don't think that's what he said.</p> <p>18 A No. I think there are two, two expert</p> <p>19 reports, one from Dr. Crowley and one from</p> <p>20 Dr. Longo.</p> <p>21 MS. BROWN:</p> <p>22 Q Okay. And the date of the Crowley</p> <p>23 report, please?</p> <p>24 A The -- according to the file, the</p>
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<p>1 I just want to know if you have those materials,</p> <p>2 and, if so, I'm gonna request production of them.</p> <p>3 A No. I -- I -- I don't believe that I</p> <p>4 have the full list of reference -- of literature</p> <p>5 cited from that -- from this paper --</p> <p>6 Q Okay.</p> <p>7 A -- now --</p> <p>8 Q Now, Taher --</p> <p>9 A -- but I'd have to check.</p> <p>10 Q Sorry.</p> <p>11 The Taher paper did not inform your --</p> <p>12 the opinions contained in your report dated</p> <p>13 November of 2018; correct?</p> <p>14 A Correct, as written.</p> <p>15 Q Okay. Are there any additional</p> <p>16 documents that either you or your counsel have</p> <p>17 brought with you here today in response to</p> <p>18 Exhibit 1, the Notice of Deposition?</p> <p>19 A So I'm not sure how to answer that</p> <p>20 accurately, but I would say there's a -- I've</p> <p>21 been provided with -- since the completion of my</p> <p>22 report, I've been provided with reports from</p> <p>23 other experts in the -- in the case.</p> <p>24 Q Okay.</p>	<p>1 date -- the modified date is November 28, 2018.</p> <p>2 Q And --</p> <p>3 A Whether that was the written date, I --</p> <p>4 I don't know.</p> <p>5 Q And the Longo report, do you know the</p> <p>6 date of that?</p> <p>7 A It is listed as August 2nd, 2017, in</p> <p>8 the title. And then there's a -- sorry. There's</p> <p>9 a second Longo report, 2018, which has a</p> <p>10 November 28, 2018, date. So my -- my apologies.</p> <p>11 To correct, there are two expert reports from</p> <p>12 Dr. Longo.</p> <p>13 Q Got it.</p> <p>14 MS. O'DELL:</p> <p>15 So when you were talking about --</p> <p>16 MS. BROWN:</p> <p>17 Counsel, no. Huh-uh. No. We -- I'm</p> <p>18 gonna ask questions, and he's gonna answer. We</p> <p>19 are not going to have you testify. You are not</p> <p>20 to testify about the expert reports.</p> <p>21 MS. O'DELL:</p> <p>22 I'm not gonna --</p> <p>23 You asked him what the date of the</p> <p>24 report was.</p>

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<p>1 MS. BROWN: 2 He -- then he will answer, counsel. 3 You can't testify. 4 MS. O'DELL: 5 He gave you the date of the file -- the 6 file date -- 7 MS. BROWN: 8 That's fine. 9 MS. O'DELL: 10 -- not the date -- 11 MS. BROWN: 12 On redirect, you are welcome to clean 13 up whatever you need to. But we're not gonna 14 have your testimony on the record about dates of 15 expert reports. 16 A So, looking at the report itself, the 17 date of the Longo report is November 14th, 2018. 18 MS. BROWN: 19 Q And were you provided -- 20 A The -- would you like the date of the 21 earlier report? 22 Q That would be terrific. 23 A It's August 2nd, 2017. 24 Q Great.</p>	<p>1 MS. BROWN: 2 Q How did you receive them? Was it email 3 or hard copy? 4 A Neither. They were made available 5 through a shared storage. 6 Q And would you have received an email 7 alerting you to their existence on a shared file? 8 MS. O'DELL: 9 Dr. Levy, communications between 10 counsel are -- are subject to the work product 11 privilege. 12 So to the degree you're asking him to 13 convey what was in a communication, then I'll 14 object to that and instruct you not to discuss 15 communications between counsel. 16 MS. BROWN: 17 Q Which the question does not ask for, 18 Doctor. 19 MS. O'DELL: 20 I believe it does. 21 MS. BROWN: 22 Q Here's what I want to know. Did you 23 rely on any other expert reports in forming your 24 opinions in this case?</p>
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<p>1 Were you provided the two Longo reports 2 and the Dr. Crowley report by plaintiffs' 3 counsel? 4 A Yes. 5 Q Do you recall when? 6 A Not specifically. It was, obviously, 7 by their date, sometime after their completion. 8 So the Crowley report and the later 2018 Longo 9 report were sometime in November or December 10 2018. 11 There's -- I've also had an opportunity 12 to review a number of -- several other expert 13 reports which are not with me today. 14 Q Do you have a listing of the additional 15 expert reports you were provided with? 16 A I'd have to -- I could certainly -- I'd 17 have to provide it. I don't, off the top of my 18 head, recall all of them. There was probably 19 approximately a dozen. 20 Q Were all of the plaintiff expert 21 reports sent to you at once? 22 MS. O'DELL: 23 Object to the form. 24 A I'm not -- I'm not certain.</p>	<p>1 A To -- to my -- the content of my 2 report, no. 3 Q Did you receive the Crowley and two 4 Longo reports after you had already completed 5 your report in this case? 6 MS. O'DELL: 7 Object to the form. 8 A No. There was -- if I recall -- and 9 the -- at least the earlier Longo report -- and 10 I'd have to review the specifics -- at least the 11 earlier Longo report was reviewed and was 12 included in the content in the report. 13 And I would have to -- since the later 14 Longo report and then the final version of this 15 report were quite close together, I don't recall 16 if they overlapped or not. I'd have to review 17 the -- which references I used in here, which 18 will just take a moment. 19 So, yes, the -- I did include both 20 Longo reports. 21 Q The second Longo report was finalized 22 two days prior to your report. Is that right? 23 A Finalized, yes. 24 Q Did you see a draft of Longo's 2018</p>

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<p>1 report?</p> <p>2 A Yes. And the --</p> <p>3 Q And did you --</p> <p>4 A And as to when I saw the draft, I</p> <p>5 believe it was -- and it was sometime in the fall</p> <p>6 and/or when reports were being revised and</p> <p>7 expanded as more literature became available.</p> <p>8 Q Prior to Longo finalizing and signing</p> <p>9 his expert report in the MDL, you had access to a</p> <p>10 draft of that report; is that right?</p> <p>11 MS. O'DELL:</p> <p>12 Object to the form.</p> <p>13 A I can't speak to -- to that accurately.</p> <p>14 MS. BROWN:</p> <p>15 Q I thought you just testified you saw a</p> <p>16 version of the Longo 2018 report that was not</p> <p>17 final. Is that correct?</p> <p>18 MS. O'DELL:</p> <p>19 Object to the form.</p> <p>20 A I'd have to -- I'd have to review</p> <p>21 my -- the -- the literature that I used for the</p> <p>22 report to accurately answer your question.</p> <p>23 MS. BROWN:</p> <p>24 Q Well, your report doesn't say a draft,</p>	<p>1 Q Did you type the expert report that</p> <p>2 we've marked as Exhibit 2 yourself?</p> <p>3 A I did.</p> <p>4 Q Did you write all contents of Exhibit 2</p> <p>5 yourself?</p> <p>6 A I did.</p> <p>7 Q Were there parts of your report that</p> <p>8 you lifted from other published articles?</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form.</p> <p>11 A Could you describe "lifted"?</p> <p>12 MS. BROWN:</p> <p>13 Q Did you take the words of other authors</p> <p>14 and put them in your expert report as Exhibit 2?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form.</p> <p>17 A No. My -- my -- so my report is a</p> <p>18 review of the available literature at the time</p> <p>19 that the report was being developed. So, as</p> <p>20 such, it describes that -- that literature.</p> <p>21 As far as did I specifically copy words</p> <p>22 from other reports, no.</p> <p>23 MS. BROWN:</p> <p>24 Q Did you work with another plaintiff</p>
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<p>1 and I'm wondering if you ever saw a non-finalized</p> <p>2 copy of the Longo report.</p> <p>3 A I didn't have an opportunity to compare</p> <p>4 the finalized Longo report to a -- what may be a</p> <p>5 draft or not to accurately answer your question</p> <p>6 if I saw a draft that was substantially different</p> <p>7 than what's referenced as the final.</p> <p>8 Q There were two days between Longo</p> <p>9 serving his report and you serving your report.</p> <p>10 Does that help orient you as to whether you saw a</p> <p>11 draft or you saw the final version?</p> <p>12 A Certainly possible I saw the final</p> <p>13 version.</p> <p>14 Q How many hours did you spend on your</p> <p>15 report in this case, Doctor?</p> <p>16 A The initial draft of the report? The</p> <p>17 initial writing of the report?</p> <p>18 Q In total, how many hours did you spend</p> <p>19 writing your report?</p> <p>20 A It was 20 hours initially, and then it</p> <p>21 would be -- it would be difficult to provide an</p> <p>22 accurate answer for the rest of that. I would</p> <p>23 say an additional few hours that I counted as</p> <p>24 revision.</p>	<p>1 expert on the report that we've marked as</p> <p>2 Exhibit 2?</p> <p>3 A I did not.</p> <p>4 Q Do you know who Dr. Zelikoff is?</p> <p>5 A The name's not familiar to me.</p> <p>6 Q Did you review a draft of</p> <p>7 Dr. Zelikoff's report before submitting your own?</p> <p>8 A I did not.</p> <p>9 Q Do you think that --</p> <p>10 A Not that I'm aware of.</p> <p>11 Q Do you have any explanation as to why a</p> <p>12 paragraph in your report is the same as a</p> <p>13 paragraph in Dr. Zelikoff's report?</p> <p>14 MS. O'DELL:</p> <p>15 Object to the form.</p> <p>16 A I -- without knowing -- without seeing</p> <p>17 the paragraph in both reports would be -- I can't</p> <p>18 comment.</p> <p>19 MS. BROWN:</p> <p>20 Q Let's mark as Exhibit 8 the expert</p> <p>21 report of Dr. Judith Zelikoff, Ph.D.</p> <p>22 (DEPOSITION EXHIBIT NUMBER 8</p> <p>23 WAS MARKED FOR IDENTIFICATION.)</p> <p>24 MS. BROWN:</p>

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<p style="text-align: right;">Page 50</p> <p>1 Q Is this something you've seen --</p> <p>2 Oh, sorry. Can I --</p> <p>3 It's okay, actually. It will flag it</p> <p>4 for you?</p> <p>5 Is this a report that you've seen</p> <p>6 before, Doctor?</p> <p>7 A I'll have to see it before I answer.</p> <p>8 Q I'm handing you what we've marked as</p> <p>9 Exhibit 8, which is the expert report of</p> <p>10 Dr. Judith Zelikoff. Is this one of the reports</p> <p>11 that you reviewed prior -- you reviewed at all?</p> <p>12 A I would have -- I would actually have</p> <p>13 to review my -- the literature that I reviewed</p> <p>14 in -- the totality of the literature that I</p> <p>15 reviewed, which I could answer that after a</p> <p>16 break, if necessary. But I don't recall,</p> <p>17 specifically recall, this report under</p> <p>18 Dr. Zelikoff's name. But it is certainly</p> <p>19 possible that I may have seen...</p> <p>20 Q Let's look at page 5 of your report,</p> <p>21 Doctor.</p> <p>22 A Okay.</p> <p>23 Q And why don't you put that side by side</p> <p>24 with page 20 of Dr. Zelikoff's report. And the</p>	<p style="text-align: right;">Page 52</p> <p>1 A They are --</p> <p>2 Q The next sentence --</p> <p>3 A Just one moment, please. I'm just</p> <p>4 making sure. Your question was are they exactly</p> <p>5 the same, and I'm just confirming if they're</p> <p>6 exactly the same.</p> <p>7 So, yes, I agree they're exactly the</p> <p>8 same.</p> <p>9 Q You have reviewed them and satisfied</p> <p>10 yourself that that -- those two sentences are</p> <p>11 exactly the same; correct?</p> <p>12 MS. O'DELL:</p> <p>13 Object to the form.</p> <p>14 A There's a single sentence in each</p> <p>15 report that is exactly the same. But important</p> <p>16 to comment that this single sentence is a -- is a</p> <p>17 basic biological premise of cancer, and, so,</p> <p>18 there's no surprise that two expert witnesses</p> <p>19 offering opinions on the role of -- or the</p> <p>20 biological plausibility or mechanisms of</p> <p>21 development of cancer would introduce a</p> <p>22 fundamental premise in the same manner.</p> <p>23 MS. BROWN:</p> <p>24 Q No surprise that you experts would have</p>
<p style="text-align: right;">Page 51</p> <p>1 paragraph in Dr. Zelikoff's report that I want to</p> <p>2 direct you to is the first full paragraph on</p> <p>3 page 20 that begins "Genetic mutations."</p> <p>4 Do you see that?</p> <p>5 A I do.</p> <p>6 Q And the paragraph of your report I want</p> <p>7 to direct you to is the paragraph on page 5 that</p> <p>8 begins "Both inherited."</p> <p>9 Do you see that?</p> <p>10 A I do.</p> <p>11 Q Okay. The first sentence of that</p> <p>12 paragraph in your report reads, "Both inherited</p> <p>13 and acquired gene -- and acquired gene mutations</p> <p>14 work together to cause cancer."</p> <p>15 Do you see that?</p> <p>16 A I do.</p> <p>17 Q The third sentence of the paragraph I</p> <p>18 directed you to in Dr. Zelikoff's report is</p> <p>19 identical and reads, "Both inherited and acquired</p> <p>20 gene mutations work together to cause cancer."</p> <p>21 Do you see that?</p> <p>22 A I do.</p> <p>23 Q Those two sentences are exactly the</p> <p>24 same, are they not?</p>	<p style="text-align: right;">Page 53</p> <p>1 one sentence that's the same? Is that what</p> <p>2 you're saying?</p> <p>3 MS. O'DELL:</p> <p>4 Objection. That's not what he said.</p> <p>5 Misrepresents his testimony.</p> <p>6 A I'm saying that both would -- both</p> <p>7 reports detail a fundamental aspect as they</p> <p>8 would -- based on the current understanding of</p> <p>9 the -- that both inherited and acquired gene</p> <p>10 mutations work in concert to cause cancer.</p> <p>11 MS. BROWN:</p> <p>12 Q Look at the next sentence on page 20 of</p> <p>13 Dr. Zelikoff's report. It reads as follows:</p> <p>14 "Even if one has inherited a genetic mutation</p> <p>15 that predisposes one to cancer," comma, "that</p> <p>16 doesn't mean he or she is certain to get cancer."</p> <p>17 Did I read that correctly?</p> <p>18 A You did.</p> <p>19 Q And let's go back to page 5 of your</p> <p>20 report. Skip ahead, if you would -- one, two,</p> <p>21 three -- four sentences to where you were and</p> <p>22 find the sentence that begins "Even."</p> <p>23 Are you with me?</p> <p>24 A I am.</p>

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<p style="text-align: right;">Page 54</p> <p>1 Q And your report at page 5 reads, "Even 2 if one has inherited a genetic mutation that 3 predisposes one to cancer," comma, "that doesn't 4 mean he or she is certain to get cancer." 5 Did I read that correctly? 6 A You did. 7 Q That's the exact same sentence we just 8 read in Dr. Zelikoff's report; correct? 9 A It is. 10 Q So now we have two sentences that are 11 exactly the same in your report and 12 Dr. Zelikoff's report. Correct? 13 MS. O'DELL: 14 Object to the form. 15 A You have two sentences that are written 16 the same but certainly not in precisely the same 17 context or organization in the total report. 18 MS. BROWN: 19 Q We have two sentences that are 20 word-for-word identical in two of the plaintiffs' 21 expert reports in this litigation. Is that fair? 22 MS. O'DELL: 23 Objection. Asked and answered. 24 A So reading your earlier question, you</p>	<p style="text-align: right;">Page 56</p> <p>1 identical to your report; correct? 2 A We have. 3 Q Do you have any explanation for why 4 that would be? 5 A I do. 6 Q What's that? 7 A That these -- each of these sentences 8 are describing basic introductory information 9 around the relationship between cancer and 10 genetic mutation. 11 Q And each of you described it with the 12 exact same words? 13 A Apparently so. 14 Q Let's keep going. 15 Page 20 of Dr. Zelikoff's report, 16 picking up where we left off, Dr. Zelikoff 17 writes: "The inherited gene mutation could 18 instead make one more likely to develop cancer 19 when exposed to certain cancer-causing 20 substances." 21 Do you see that? 22 A I do. 23 Q And let's go back to where we were in 24 your report, on page 5. "The inherited gene</p>
<p style="text-align: right;">Page 55</p> <p>1 asked, "Is that the same exact sentence we just 2 read in Dr. Zelikoff's report; correct?" And my 3 answer was "It is." And it remains the same. 4 Q Let's keep going. 5 Next sentence, at page 20 in 6 Dr. Zelikoff's report, states as follows: 7 "Rather," comma, "one or more additional gene 8 mutations may be needed to cause cancer." 9 Did I read that correctly? 10 A You did. 11 Q Let's go back to page 4 -- excuse me -- 12 page 5 of your report where we just were. And 13 you write: "Rather," comma, "one or more 14 additional gene mutations may be needed to cause 15 cancer." Correct? 16 A Correct. 17 Q That is the identical sentence from 18 Dr. Zelikoff's report. Correct? 19 A Starting with "Rather, one or more 20 additional gene mutations may be needed to cause 21 cancer." 22 Yes, correct. 23 Q So we now have identified three 24 sentences in Dr. Zelikoff's report that are</p>	<p style="text-align: right;">Page 57</p> <p>1 mutation could instead make one more likely to 2 develop cancer when exposed to a certain 3 cancer-causing substance." 4 Do you see that? 5 A I do. 6 Q And other than the tense in that last 7 sentence, they, too, are identical. Correct? 8 A So they're -- they're certainly similar 9 sentences, but that -- I believe the tense is an 10 important difference between them. 11 Again, as I stated, that these are 12 introductory and fundamental perspectives on 13 cancer and that, in this case, two expert 14 witnesses have summarized those things in a 15 similar fashion. 16 Q It doesn't strike you as odd that four 17 sentences are identical from two expert reports? 18 MS. O'DELL: 19 Object to the form. 20 A Four sentences are not identical. 21 MS. BROWN: 22 Q There's one small change in a tense. 23 That's it. Right, Doctor? 24 MS. O'DELL:</p>

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<p style="text-align: right;">Page 58</p> <p>1 Object to the form.</p> <p>2 A There -- there are -- there are three</p> <p>3 sentences which are, when considered</p> <p>4 individually, they are the same words. When you</p> <p>5 consider the -- now the group of those four</p> <p>6 sentences together between the two reports, they</p> <p>7 are clearly different organization with</p> <p>8 significantly more information between those</p> <p>9 identical sentences in one or the other.</p> <p>10 So the suggestion that they were -- one</p> <p>11 report was copied into the other, I would say it</p> <p>12 is equally interesting that they are more</p> <p>13 different than they are alike, other than the</p> <p>14 wording of three sentences.</p> <p>15 MS. BROWN:</p> <p>16 Q Did someone other than you write the</p> <p>17 sentences we've just been looking at in your</p> <p>18 report?</p> <p>19 A No.</p> <p>20 Q Did you consult the Mayo Clinic's</p> <p>21 website in connection with writing your report?</p> <p>22 A I don't believe so.</p> <p>23 Q Do you consider the Mayo Clinic's</p> <p>24 website to be authoritative -- an authoritative</p>	<p style="text-align: right;">Page 60</p> <p>1 Q -- next to your report, which remains</p> <p>2 Exhibit 2. And I will direct you to the second</p> <p>3 page of the Mayo Clinic printout, the section</p> <p>4 titled "Causes."</p> <p>5 Are you with me?</p> <p>6 A Second page.</p> <p>7 Q Double-sided. Flip it over.</p> <p>8 A Yes.</p> <p>9 Q Okay. And I'll direct you to page 3 of</p> <p>10 your report entitled "The Role of Gene Mutations</p> <p>11 in the Development of Cancer."</p> <p>12 A Uh-huh.</p> <p>13 Q Starting with Exhibit 9, the Mayo</p> <p>14 Clinic website, under a section entitled</p> <p>15 "Causes," the Mayo Clinic writes, "Cancer is</p> <p>16 caused by changes" -- parentheses --</p> <p>17 "(mutations) to the DNA within cells."</p> <p>18 Do you see that?</p> <p>19 A I do.</p> <p>20 Q And, looking at page 3 of your report,</p> <p>21 Doctor, that same sentence or sentence fragment</p> <p>22 appears in the first sentence: "Cancer is caused</p> <p>23 by changes" -- parentheses -- "(mutations) to the</p> <p>24 DNA within cells."</p>
<p style="text-align: right;">Page 59</p> <p>1 source, in your view?</p> <p>2 MS. O'DELL:</p> <p>3 Object to the form.</p> <p>4 A I have no basis for that opinion. I --</p> <p>5 I haven't reviewed the Mayo Clinic website to</p> <p>6 determine that.</p> <p>7 (DEPOSITION EXHIBIT NUMBER 9</p> <p>8 WAS MARKED FOR IDENTIFICATION.)</p> <p>9 MS. BROWN:</p> <p>10 Q Handing you, Doctor, what we've marked</p> <p>11 as Exhibit 9 to your deposition, which is a</p> <p>12 printout from the Mayo Clinic website entitled</p> <p>13 "Cancer."</p> <p>14 A Uh-huh.</p> <p>15 Q I'll hand it to you. And let me know</p> <p>16 if this is something that you've ever seen</p> <p>17 before.</p> <p>18 A Not that I recall.</p> <p>19 Q Did you take any language from the Mayo</p> <p>20 Clinic website to use in your report?</p> <p>21 A No.</p> <p>22 Q Let's take a -- I want you to put the</p> <p>23 Mayo Clinic, which we've marked as Exhibit 9 --</p> <p>24 A Uh-huh.</p>	<p style="text-align: right;">Page 61</p> <p>1 Correct?</p> <p>2 MS. O'DELL:</p> <p>3 Object to the form.</p> <p>4 A Say your question again. Are you</p> <p>5 asking --</p> <p>6 MS. BROWN:</p> <p>7 Q It's the same; right, Doctor?</p> <p>8 MS. O'DELL:</p> <p>9 Object to the form.</p> <p>10 A There are eight words or ten words that</p> <p>11 are the same in this first sentence, again, both</p> <p>12 describing some of the fundamental premise of</p> <p>13 cancer and its -- in its description.</p> <p>14 MS. BROWN:</p> <p>15 Q Let's go to the second sentence in the</p> <p>16 Mayo Clinic website, which reads, "The DNA inside</p> <p>17 a cell is packaged into a large number of</p> <p>18 individual genes, each of which contains a set of</p> <p>19 instructions telling the cell what functions to</p> <p>20 perform," comma, "as well as how to grow and</p> <p>21 divide."</p> <p>22 Do you see that?</p> <p>23 A I do.</p> <p>24 Q And a nearly identical version of that</p>

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<p style="text-align: right;">Page 62</p> <p>1 sentence appears in your report at page 3 where</p> <p>2 you state, "The DNA that makes up our genetic</p> <p>3 code is organized into a large number of</p> <p>4 individual genes, each of which contains a</p> <p>5 specific subset of instructions telling the cell</p> <p>6 what functions to perform," comma, "as well as</p> <p>7 how to grow and divide."</p> <p>8 Do you see that?</p> <p>9 A I do.</p> <p>10 Q Do you notice that nearly all the words</p> <p>11 are the same as the Mayo Clinic's?</p> <p>12 MS. O'DELL:</p> <p>13 Objection to form.</p> <p>14 A I, again -- we -- we have another</p> <p>15 example of similar language describing</p> <p>16 introductory and fundamental aspects surrounding</p> <p>17 the basics of cancer biology.</p> <p>18 MS. BROWN:</p> <p>19 Q Back to the Mayo Clinic next sentence.</p> <p>20 Quote: "Errors in the instructions can cause the</p> <p>21 cell to stop its normal function and may allow a</p> <p>22 cell to become cancerous."</p> <p>23 Do you see that?</p> <p>24 A I do.</p>	<p style="text-align: right;">Page 64</p> <p>1 subparagraph titled "Loss of DNA Repair."</p> <p>2 Are you with me?</p> <p>3 A Yes.</p> <p>4 Q I'm gonna read you two sentences from</p> <p>5 the Mayo Clinic. Tell me if I read them</p> <p>6 correctly.</p> <p>7 "DNA repair genes look for errors in a</p> <p>8 cell's DNA and make corrections. A mutation in a</p> <p>9 DNA repair gene may mean that other errors aren't</p> <p>10 corrected, leading cells to become cancerous."</p> <p>11 Do you see those two sentences, Doctor?</p> <p>12 A I do.</p> <p>13 Q Those are two sentences written by the</p> <p>14 folks who produce the Mayo Clinic's website;</p> <p>15 correct?</p> <p>16 A I -- I have no knowledge of who wrote</p> <p>17 that.</p> <p>18 Q The same two sentences appear in your</p> <p>19 report on page 4. Quote: "DNA repair genes look</p> <p>20 for errors in a cell's DNA and make corrections.</p> <p>21 A mutation in a DNA repair gene may mean that</p> <p>22 other errors aren't corrected, leading cells to</p> <p>23 become cancerous."</p> <p>24 Do you see that?</p>
<p style="text-align: right;">Page 63</p> <p>1 Q Back to your report at page 3. An</p> <p>2 identical sentence: "Errors in the instruction</p> <p>3 can cause the cell to stop its normal function</p> <p>4 and may allow a cell to become cancerous."</p> <p>5 Do you see that?</p> <p>6 A I do.</p> <p>7 Q Does that strike you as strange?</p> <p>8 MS. O'DELL:</p> <p>9 Object to the form.</p> <p>10 A Strange in what way?</p> <p>11 MS. BROWN:</p> <p>12 Q That your expert report in this</p> <p>13 litigation contains identical sentences to the</p> <p>14 Mayo Clinic's website.</p> <p>15 MS. O'DELL:</p> <p>16 Objection. Misstates the report.</p> <p>17 A I -- I don't find it surprising in the</p> <p>18 least.</p> <p>19 MS. BROWN:</p> <p>20 Q Let's turn to page 4 of your report,</p> <p>21 please. And I'll direct you to the final bullet</p> <p>22 on the same page of the Mayo Clinic website you</p> <p>23 were just looking at. The section of your report</p> <p>24 on page 4 I'd like to direct you to is the</p>	<p style="text-align: right;">Page 65</p> <p>1 A I do.</p> <p>2 Q Those two sentences are identical in</p> <p>3 the Mayo Clinic's website and your report. True?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form.</p> <p>6 A Again, we have fund- -- basic</p> <p>7 information that provides an introductory</p> <p>8 description of the basics of cancer which is used</p> <p>9 as -- as an inform- -- informatory foundation for</p> <p>10 latter opinions in the report but is not germane</p> <p>11 to the -- to the opinion in my report.</p> <p>12 And, again, as stated before, that</p> <p>13 succinct fundamental information regarding cancer</p> <p>14 biology in two sources that state things</p> <p>15 succinctly and clearly in layman's language</p> <p>16 are -- are similar or even identical, again, does</p> <p>17 not surprise me.</p> <p>18 MS. BROWN:</p> <p>19 Q We read at least four sentences that</p> <p>20 are identical to the Mayo Clinic. Would you</p> <p>21 agree?</p> <p>22 MS. O'DELL:</p> <p>23 Objection to form. The sentences are</p> <p>24 not identical.</p>

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<p>1 MS. BROWN: 2 Counsel, form. 3 A There are some similar -- there are 4 some similarly stated sentences that 5 you're -- that you've taken out of context in 6 both cases to find them identical. So I -- I 7 agree that they're identical, but, again, 8 don't -- don't necessarily am surprised since I 9 have no knowledge of where the information from 10 the Mayo website was taken from. 11 MS. BROWN: 12 Q You agree a number of sentences in your 13 report are identical to a number of sentences on 14 the Mayo Clinic's website. True? 15 MS. O'DELL: 16 Object to the form. 17 A No. I agree that they're -- I don't 18 agree. There are specific wordings that are the 19 same. 20 MS. BROWN: 21 Q Doctor, do you not agree that a number 22 of the sentences we just read are identical to a 23 number of sentences that appear on the Mayo 24 Clinic's website?</p>	<p>1 from our conversation to comment on those. 2 MS. BROWN: 3 Q You have it right in front of you. We 4 just looked at them. 5 A We did. 6 Q Right? 7 A Yes. 8 Q You recall reading a number of 9 sentences in the Mayo Clinic website that match 10 word for word a number of sentences in your 11 report. True? 12 MS. O'DELL: 13 Object to the form. 14 A We've -- we've read information that 15 is -- that is similar between the two documents. 16 And, as answered, given the, again, basic 17 fundamental introduction in lay language for 18 these concepts, it is no surprise that it's the 19 same. 20 MS. BROWN: 21 Q You're not surprised to find identical 22 sentences in your report and Dr. Zelikoff's 23 report? 24 A I'm not surprised.</p>
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<p>1 MS. O'DELL: 2 Object to the form. 3 A I think we've -- we've specifically 4 gone over those individually and answered those 5 questions. 6 MS. BROWN: 7 Q And you'll agree the sentences are 8 identical? 9 MS. O'DELL: 10 Object to the form. 11 A Again, I -- I've answered -- I've 12 answered those when we went through them 13 individually. 14 MS. BROWN: 15 Q Well, I want you to answer my question 16 now. 17 You'll agree we've looked at a number 18 of sentences that are identical in your report to 19 the information on the Mayo Clinic's website; 20 correct? 21 MS. O'DELL: 22 Object to the form. Misstates his 23 testimony. 24 A I'd have to go back to the transcript</p>	<p>1 MS. O'DELL: 2 Object to the form. 3 MS. BROWN: 4 Q You are not surprised to find identical 5 sentences in your report and the Mayo Clinic? 6 MS. O'DELL: 7 Objection to form. Asked and answered. 8 A No. I -- I've answered that. 9 MS. BROWN: 10 Q You need to answer it again. 11 Are you -- 12 A I'm not surprised. 13 Q -- surprised? 14 Did you consult Wikipedia in writing 15 your expert report? 16 A I don't recall. 17 Q Do you think it's possible you might 18 have looked at Wikipedia when writing your expert 19 report in this litigation? 20 A I've -- I've looked -- I've looked at a 21 large number of sources in published literature 22 and others. 23 Q Did one of those sources include 24 Wikipedia?</p>

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<p>1 A I don't recall.</p> <p>2 Q Do you consider Wikipedia to be a</p> <p>3 scientifically reliable source?</p> <p>4 A What do you mean by scientifically</p> <p>5 reliable.</p> <p>6 Q Do you understand the concept of</p> <p>7 scientific reliability when answering a</p> <p>8 scientific question?</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form.</p> <p>11 A Again, you'd have to -- that's -- you'd</p> <p>12 have to explain your -- what scientific</p> <p>13 reliability means in the context of your</p> <p>14 question.</p> <p>15 MS. BROWN:</p> <p>16 Q What does it mean to you?</p> <p>17 A Scientific reliability? In general</p> <p>18 terms, it would mean information that comes from</p> <p>19 a peer-reviewed source.</p> <p>20 Q And Wikipedia is not peer-reviewed;</p> <p>21 correct?</p> <p>22 A Wikipedia generally reso- -- uses</p> <p>23 a -- is a summary of commonly -- at least in</p> <p>24 scientific terms, a number of peer-reviewed</p>	<p>1 And we'll mark a Wikipedia page as</p> <p>2 Exhibit 10.</p> <p>3 (DEPOSITION EXHIBIT NUMBER 10</p> <p>4 WAS MARKED FOR IDENTIFICATION.)</p> <p>5 MS. BROWN:</p> <p>6 Q I would like to direct you, Dr. Levy,</p> <p>7 to the first full paragraph in your expert report</p> <p>8 at page 7.</p> <p>9 A Uh-huh.</p> <p>10 Q Do you see that?</p> <p>11 A I do.</p> <p>12 Q And I want to direct your attention to</p> <p>13 the sentence in the middle of that paragraph that</p> <p>14 begins "BRCA1 combined."</p> <p>15 Do you see that?</p> <p>16 A Yes.</p> <p>17 MS. BROWN:</p> <p>18 Q And I want to, side by side with</p> <p>19 Wikipedia, direct your attention to the third</p> <p>20 full paragraph that begins, as well, "BRCA1</p> <p>21 combined."</p> <p>22 You with me?</p> <p>23 A I am.</p> <p>24 Q Wikipedia writes, "BRCA1 combines with</p>
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<p>1 sources, but it is --</p> <p>2 So from a true peer-review perspective,</p> <p>3 Wikipedia actually is peer-reviewed in the sense</p> <p>4 that anyone can contribute and edit the</p> <p>5 information in Wikipedia.</p> <p>6 Q Including our kids; right?</p> <p>7 MS. O'DELL:</p> <p>8 Object to the form.</p> <p>9 A Possible.</p> <p>10 MS. BROWN:</p> <p>11 Q Anyone in the world could edit a</p> <p>12 Wikipedia page. True?</p> <p>13 A I believe so.</p> <p>14 Q Is it your testimony, Doctor, that</p> <p>15 information from Wikipedia is a reliable resource</p> <p>16 when answering a scientific question?</p> <p>17 A No, that is not my testimony. That is</p> <p>18 not my testimony, no.</p> <p>19 Q Do you -- do you think you used</p> <p>20 Wikipedia here in writing your report?</p> <p>21 A Again, I -- I -- I don't recall using</p> <p>22 Wikipedia specifically.</p> <p>23 Q Okay. Let's take a look at your report</p> <p>24 at page 7, Doctor.</p>	<p>1 other tumor suppressors, DNA damage sensors, and</p> <p>2 single transducers to form a large multi-subunit</p> <p>3 protein complex known as BRCA1-associated genome</p> <p>4 surveillance complex" -- parens --</p> <p>5 "BAC-" -- excuse me -- "(BASC)," end parens.</p> <p>6 Do you see that?</p> <p>7 A I do.</p> <p>8 Q Turning to your report, page 7, you</p> <p>9 write, "BRCA1 combines with other tumor</p> <p>10 suppressors," comma, "DNA damage sensors, and</p> <p>11 signal transducers to form a large multi-subunit</p> <p>12 protein complex known as the BRCA1-associated</p> <p>13 genome surveillance complex" -- parens --</p> <p>14 (BASC)."</p> <p>15 Correct?</p> <p>16 A That is correct.</p> <p>17 Q Those two sentences, Doctor, are</p> <p>18 identical.</p> <p>19 A It appears so, yes.</p> <p>20 Q Okay.</p> <p>21 A Except for a -- the reference included</p> <p>22 on the Wikipedia page is not included in my</p> <p>23 report.</p> <p>24 Q Wikipedia has cited a reference, and</p>

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<p>1 your sentence stands without a reference. Is</p> <p>2 that right?</p> <p>3 A That's right.</p> <p>4 Q Other than the footnote, the two</p> <p>5 sentences we just read are identical. True?</p> <p>6 A Both sentences state the same fact in</p> <p>7 the same way. So, similar to our earlier</p> <p>8 discussions, we've now seen a large collection of</p> <p>9 fundamental factual information with -- with</p> <p>10 accurate information from now a number of sources</p> <p>11 that are stated in similar ways through</p> <p>12 Wikipedia, other expert reports, and websites all</p> <p>13 about the fundamentals of cancer.</p> <p>14 Q The two sentences we just read, Doctor,</p> <p>15 are identical. Correct?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A We read one sentence in Wikipedia.</p> <p>19 MS. BROWN:</p> <p>20 Q And it is identical. True?</p> <p>21 A Yes. The wording is the same. With,</p> <p>22 of course, Wikipedia, as you already stated,</p> <p>23 being editable by anybody and can pull that</p> <p>24 content from anywhere, and it's the -- I'd have</p>	<p>1 Q I'm sorry. What did we mark the</p> <p>2 Coussens as? 12?</p> <p>3 A Twelve.</p> <p>4 Q That should have been 11.</p> <p>5 We have marked the Coussens' article</p> <p>6 now correctly as Exhibit 11, and I'll direct you</p> <p>7 to the last two sentences of the first full</p> <p>8 paragraph. Put that, if you would, Doctor, side</p> <p>9 by side with your report at page 9, sentence that</p> <p>10 begins "in contrast," both sentences that begin</p> <p>11 "in contrast."</p> <p>12 Are you with me?</p> <p>13 A I am.</p> <p>14 Q All right. So, in this published</p> <p>15 article, Ms. or Dr. Coussens writes, "In</p> <p>16 contrast, proliferating cells that sustain</p> <p>17 DNA" --</p> <p>18 MS. O'DELL:</p> <p>19 Excuse me, Alli. Sorry. Tell me, are</p> <p>20 you in the second paragraph?</p> <p>21 MS. BROWN:</p> <p>22 I'm on the end of the first full</p> <p>23 paragraph.</p> <p>24 MS. O'DELL:</p>
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<p>1 to review -- I'd have to look to see what</p> <p>2 reference 16 in Wikipedia is. But it's certainly</p> <p>3 possible that I and Wikipedia summarized the same</p> <p>4 information from the same source.</p> <p>5 Q Let's go to page 9 of your report. One</p> <p>6 of the articles that you relied on is an article</p> <p>7 by Lisa Coussens and Zena Werb. Do you recall</p> <p>8 that?</p> <p>9 A That does sound familiar, but I'll have</p> <p>10 to verify.</p> <p>11 Q Handing you what we've marked as</p> <p>12 Exhibit 12 [sic] to your report, the Coussens and</p> <p>13 Werb article.</p> <p>14 (DEPOSITION EXHIBIT NUMBER 11</p> <p>15 WAS MARKED FOR IDENTIFICATION.)</p> <p>16 A Yes, this is a -- this is a review.</p> <p>17 This is an insight review article, which, similar</p> <p>18 to my report, is likely consolidating information</p> <p>19 from the research knowledge.</p> <p>20 MS. BROWN:</p> <p>21 Q I'd like to direct you to the last two</p> <p>22 sentences of Exhibit 10, the Coussens' article,</p> <p>23 the last two sentences in the first paragraph.</p> <p>24 A Exhibit 10 or 12?</p>	<p>1 Sorry. I thought you were in the first</p> <p>2 full paragraph.</p> <p>3 MS. BROWN:</p> <p>4 Begins "In contrast."</p> <p>5 MS. O'DELL:</p> <p>6 Okay.</p> <p>7 MS. BROWN:</p> <p>8 And we have that side by side with</p> <p>9 Dr. Levy's report, page 9, the paragraph that</p> <p>10 also begins "In contrast."</p> <p>11 MS. O'DELL:</p> <p>12 Thank you.</p> <p>13 MS. BROWN:</p> <p>14 Q Dr. Coussens writes, "In contrast,</p> <p>15 proliferating cells that sustain DNA damage</p> <p>16 and/or mutagenic assault" -- parens -- "(for</p> <p>17 example, initiated cells), continue to</p> <p>18 proliferate in microenvironments rich in</p> <p>19 inflammatory cells and growth/survival factors</p> <p>20 that support their growth."</p> <p>21 Do you see that sentence?</p> <p>22 A I do.</p> <p>23 Q The next sentence reads, "In a sense,"</p> <p>24 comma, "tumors act as wounds that fail to heal."</p>

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<p style="text-align: right;">Page 78</p> <p>1 See that?</p> <p>2 A I do.</p> <p>3 Q Directing your attention to page 9 of</p> <p>4 your report, Doctor, you write, "In contrast,"</p> <p>5 comma, "proliferating cells that sustain DNA</p> <p>6 damage and/or mutagenic insult -- parens -- "(for</p> <p>7 example," comma, "initiated cells)," end paren,</p> <p>8 "continue to proliferate in microenvironments</p> <p>9 rich in inflammatory cells and growth/survival</p> <p>10 factors that support their growth," period. "In</p> <p>11 a sense, tumors act as wounds that fail to heal."</p> <p>12 Do you see that?</p> <p>13 A I do.</p> <p>14 Q Except for one word, Doctor, those two</p> <p>15 sentences, including the slashes and the</p> <p>16 parentheses, are identical. Correct?</p> <p>17 MS. O'DELL:</p> <p>18 Object to the form.</p> <p>19 A Those two sentences are similar.</p> <p>20 MS. BROWN:</p> <p>21 Q Except for one word, those two</p> <p>22 sentences are identical. True?</p> <p>23 MS. O'DELL:</p> <p>24 Object to the form. Asked and</p>	<p style="text-align: right;">Page 80</p> <p>1 Q My question, Doctor, was: Except for</p> <p>2 one word, the two sentences we just read from</p> <p>3 Coussens are identical to the two sentences in</p> <p>4 your report. Is that correct?</p> <p>5 MS. O'DELL:</p> <p>6 Object to the form.</p> <p>7 A So, I -- as -- as stated, the two</p> <p>8 sentences are similar.</p> <p>9 MS. BROWN:</p> <p>10 Q Except for one word, they are</p> <p>11 identical. Is that correct?</p> <p>12 MS. O'DELL:</p> <p>13 Object to the form. He's asked --</p> <p>14 you've asked the question. He's answered your</p> <p>15 question.</p> <p>16 A Again, the two sentences are similar.</p> <p>17 MS. BROWN:</p> <p>18 Q Do you understand "identical," what</p> <p>19 "identical" means?</p> <p>20 A Yes. Exactly the same.</p> <p>21 Q Okay. Except for one word, those two</p> <p>22 sentences are exactly the same in the Coussens</p> <p>23 article and your report. True?</p> <p>24 MS. O'DELL:</p>
<p style="text-align: right;">Page 79</p> <p>1 answered.</p> <p>2 A Yeah. I'd certainly appreciate the</p> <p>3 similarity between the -- between the two. But</p> <p>4 that's -- again, as we've been discussing now for</p> <p>5 an extensive amount of time, in the introductory</p> <p>6 review content of the report --</p> <p>7 In fact, I reference the Coussens and</p> <p>8 Werb paper, so certainly it's not a surprise that</p> <p>9 wording is similar between them and used similar</p> <p>10 language to describe, again, these factual</p> <p>11 aspects of fundamental cancer biology, including</p> <p>12 similar references.</p> <p>13 MS. O'DELL:</p> <p>14 Excuse me. My microphone is broken.</p> <p>15 VIDEOGRAPHER:</p> <p>16 It's still working. You're good. You</p> <p>17 can just lay it on the table and we'll fix it at</p> <p>18 a break.</p> <p>19 MS. O'DELL:</p> <p>20 And we've been going about an hour and</p> <p>21 13 minutes.</p> <p>22 MS. BROWN:</p> <p>23 I'm about to finish up this section.</p> <p>24 We'll take a break.</p>	<p style="text-align: right;">Page 81</p> <p>1 Object to the form. Asked and</p> <p>2 answered.</p> <p>3 A And we're -- we're saying the same</p> <p>4 thing in different ways, which is that the two</p> <p>5 sentences are similar, stating factual</p> <p>6 information about fundamental cancer biology and</p> <p>7 in two similar review articles.</p> <p>8 MS. BROWN:</p> <p>9 Q And the only difference is one word.</p> <p>10 Correct?</p> <p>11 A Two sentences are similar.</p> <p>12 Q My question was: The only difference</p> <p>13 is one word. True?</p> <p>14 A Let me review again to be sure that we</p> <p>15 would -- before answering.</p> <p>16 Taken out of context, those two</p> <p>17 sentences are similar.</p> <p>18 Q My question was, Doctor, the only</p> <p>19 difference is one word. Is that correct?</p> <p>20 MS. O'DELL:</p> <p>21 Objection to the form. Asked and</p> <p>22 answered.</p> <p>23 A You know, I think we've -- we've</p> <p>24 answered this a number of times, that the two</p>

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<p>1 sentences are different in their context and in 2 terms of paragraph, but they are similar in 3 structure and similar in wording. 4 But, as you stated, with the exception 5 of the -- so they're not. So in a language 6 perspective, they're not identical. They're 7 similar. 8 MS. BROWN: 9 Let's take a break. 10 VIDEOGRAPHER: 11 Going off -- going off the record. The 12 time is 10:15 a.m. 13 (OFF THE RECORD.) 14 VIDEOGRAPHER: 15 We're back on the record. The time is 16 10:25 a.m. 17 MS. BROWN: 18 Q Doctor, I am handing you what I have 19 marked as Deposition Exhibit 12 and 13. These 20 are additional documents your counsel identified 21 for us this morning as something you have seen 22 since your report. 23 (DEPOSITION EXHIBITS 12 AND 13 24 WERE MARKED FOR IDENTIFICATION.)</p>	<p>1 A I have. 2 Q Have you seen the reviewer comments 3 referenced in Exhibit 13? 4 A I have not seen the reviewer comments. 5 Q Okay. Exhibit 13 does not inform the 6 opinions of your report dated November of 2018. 7 True? 8 A Exhibit 13, being the letter, that is 9 correct. It does not. 10 Q Okay. And what's Exhibit 12? 11 A Exhibit 12 appears to be a preprint 12 version of the previously mentioned paper, 13 "Molecular Basis Supporting the Association of 14 Talcum Powder Use With Increased Risk of Ovarian 15 Cancer," with the first author, Nicole Fletcher, 16 and Dr. Saed is listed as the senior or 17 corresponding author. 18 Q Did the lawyers provide you with this 19 manuscript, Doctor? 20 A Yes, in a -- but that's -- yes, they 21 did. 22 Q Do you recall when you were provided 23 with a copy of the manuscript by the plaintiffs' 24 lawyers?</p>
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<p>1 MS. BROWN: 2 Q Would you tell us what those two 3 exhibits are, please. 4 A Exhibit -- Exhibit 13 is a printed copy 5 of an email dated December 26th informing 6 Dr. Saed that a manuscript -- 7 Is it helpful to identify the 8 manuscript? 9 -- titled "Molecular Basis Supporting 10 the Association of Talcum Powder Use With 11 Increased Risk of Ovarian Cancer," submitted to 12 Reproductive Sciences, has been reviewed. The 13 comments were included in the letter. 14 Q Have you seen -- 15 A And I'm just reading the -- 16 Q Sure. 17 A It -- it appears that the -- so, 18 summarizing the letter, the manuscript has been 19 reviewed, the comments from the reviewers were 20 provided back, and the journal has informed 21 Dr. Saed that they'll accept a revised document 22 for potential publication. 23 Q Have you seen Exhibit 13 prior to this 24 morning?</p>	<p>1 A It was sometime in December toward -- 2 late in the year. The exact date, I'd have to 3 review when it came in. And I believe it was -- 4 and the version you have here is a more formal 5 preprint version from the -- from Manuscript 6 Central, whereas the version I received 7 was a -- it appeared to be more of a submission 8 version. 9 So commenting whether it's 10 exact -- precisely the same content, I -- I 11 wouldn't be able to say. 12 Q Fair to say, though, Doctor, since you 13 received the manuscript in December of 2018, the 14 contents of the manuscript did not inform the 15 expert report that you wrote in November of 2018; 16 correct? 17 A Actually, I would say the -- the -- I 18 would not agree, from the perspective of Dr. Saed 19 has a number of similar studies, as well as a 20 number of abstracts that I had the opportunity to 21 review that did inform some of the opinions in 22 the report. Those same information and data were 23 included in this manuscript and expanded upon 24 actually significantly.</p>

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<p>1 So the basis of my opinion includes</p> <p>2 some of the information from this manuscript, but</p> <p>3 I -- but the report does not contain the totality</p> <p>4 of this.</p> <p>5 Q Right. Because the manuscript wasn't</p> <p>6 available to you until after you wrote your</p> <p>7 report. Right?</p> <p>8 A No, that's not the case. The -- the --</p> <p>9 the research, some of the research information</p> <p>10 from this study was available in abstract form,</p> <p>11 and -- and some -- I believe a preprint from</p> <p>12 Dr. Saed.</p> <p>13 So it was -- so it was available.</p> <p>14 Portions of it were available for the report.</p> <p>15 Q Other than the abstract, did you have</p> <p>16 access to an earlier version of what we've marked</p> <p>17 as Exhibit 12?</p> <p>18 A I can't accurately answer that without</p> <p>19 comparing them.</p> <p>20 Q Where do you have stored the earlier</p> <p>21 version that you're referring to?</p> <p>22 A Let's see if I -- what I have here.</p> <p>23 So, from Dr. Saed, I have a -- used a</p> <p>24 book chapter which describes some of his</p>	<p>1 Q Okay. And I'll ask if you'd be kind</p> <p>2 enough to do that at a break. Just let us know</p> <p>3 if you had access to something other than the</p> <p>4 abstract of Dr. Saed's 2018 report at the time</p> <p>5 you wrote your report. Fair enough?</p> <p>6 A I'll make a note.</p> <p>7 MS. O'DELL:</p> <p>8 Excuse me. Object to the form.</p> <p>9 Abstracts, not one.</p> <p>10 MS. BROWN:</p> <p>11 Q Dr. Levy, you are a Ph.D.; is that</p> <p>12 correct?</p> <p>13 A Correct.</p> <p>14 Q Okay. You are not an M.D.; correct?</p> <p>15 A That's correct.</p> <p>16 Q What's your Ph.D. in, sir?</p> <p>17 A Biochemistry and genetics.</p> <p>18 Q You're not an epidemiologist. Fair?</p> <p>19 A I am not.</p> <p>20 Q Okay. And the focus of your work at</p> <p>21 HudsonAlpha is on genome sequencing. Is that</p> <p>22 right?</p> <p>23 A No. The -- the -- genome sequencing is</p> <p>24 a tool that we apply in -- in the work of my</p>
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<p>1 oxidative stress experiments that are also</p> <p>2 consistent with the information that's in the --</p> <p>3 in Exhibit 12, as well as some of his earlier</p> <p>4 review articles, and that's --</p> <p>5 Let me make sure I'm not missing</p> <p>6 anything from Fletcher, who's been...</p> <p>7 But, otherwise, the -- the experiments</p> <p>8 that were expanded upon in the formal manuscript</p> <p>9 were described in -- in abstract or, I should</p> <p>10 say, summarized form, meaning an abstract that</p> <p>11 included methods, results, and conclusions from</p> <p>12 Fletcher and colleagues in Dr. Saed's group.</p> <p>13 Q At the time you wrote your report, you</p> <p>14 had an abstract of the 2018 paper that we've</p> <p>15 marked as Exhibit 12; correct?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form. He said plural.</p> <p>18 A Yes. I had two abstracts and then</p> <p>19 possibly --</p> <p>20 I'd have to review when I received this</p> <p>21 preprint versus the final version of my report to</p> <p>22 see if they overlapped, if they're -- if I had an</p> <p>23 opportunity to review this or not.</p> <p>24 MS. BROWN:</p>	<p>1 laboratory and in my responsibilities at</p> <p>2 HudsonAlpha.</p> <p>3 Q HudsonAlpha has a team known as the</p> <p>4 Breakthrough Breast and Ovarian Cancer Team. Is</p> <p>5 that right?</p> <p>6 A I'm not familiar with that name.</p> <p>7 Q Okay.</p> <p>8 A There is a -- a group of faculty who</p> <p>9 have some funding related to breast and ovarian</p> <p>10 cancer. It's -- it's certainly possible that</p> <p>11 name was used in -- in press for some title.</p> <p>12 Q Since you're not familiar with that</p> <p>13 team, fair to say you're not a member of the</p> <p>14 Breakthrough Breast and Ovarian Cancer Team?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form.</p> <p>17 A Again, I don't -- my involvement with</p> <p>18 breast and ovarian cancer at HudsonAlpha is</p> <p>19 specific to some projects. And whether or not I</p> <p>20 was named on that team, I -- I don't know.</p> <p>21 MS. BROWN:</p> <p>22 Q There are folks at HudsonAlpha,</p> <p>23 scientists and doctors at HudsonAlpha whose</p> <p>24 practice is devoted to studying ovarian cancer.</p>

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<p style="text-align: right;">Page 90</p> <p>1 Correct?</p> <p>2 A No, that's not correct.</p> <p>3 Q Your practice is not devoted to ovarian</p> <p>4 cancer; correct?</p> <p>5 MS. O'DELL:</p> <p>6 Object to the form.</p> <p>7 A No. My -- my practice is not devoted</p> <p>8 to ovarian cancer. And -- but that was</p> <p>9 irrelevant to what I was asked to do in</p> <p>10 this -- in this particular case for</p> <p>11 the -- regarding the content of my report.</p> <p>12 MS. BROWN:</p> <p>13 Q I think I saw you've published one</p> <p>14 article regarding ovarian cancer over the course</p> <p>15 of your career. Is that right?</p> <p>16 A That sounds correct.</p> <p>17 Q You have not given any presentations</p> <p>18 regarding ovarian cancer. Is that true?</p> <p>19 A I would say that's accurate.</p> <p>20 Q You have not received any government</p> <p>21 funding to study ovarian cancer. True?</p> <p>22 A I received government funding to study</p> <p>23 breast and ovarian cancer -- this was in 2002,</p> <p>24 from the Department of Defense -- and then,</p>	<p style="text-align: right;">Page 92</p> <p>1 dating back to my early Ph.D. work, and those</p> <p>2 include cancer. So certainly the subject of</p> <p>3 inflammatory response in -- both chronic and</p> <p>4 acute, in controlling cancer has been a subject</p> <p>5 of my research for some time and certainly</p> <p>6 bridged into ovarian cancer as well as other</p> <p>7 cancer types.</p> <p>8 MS. BROWN:</p> <p>9 Q You've never published on chronic</p> <p>10 inflammation as a potential mechanism by which</p> <p>11 talcum powder causes ovarian cancer. Correct?</p> <p>12 A Not specific to talcum powder, no.</p> <p>13 Q You have never given a presentation on</p> <p>14 chronic inflammation as a mechanism for causing</p> <p>15 ovarian cancer at all; right?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A I'm thinking through my --</p> <p>19 I don't recall a specific presentation</p> <p>20 with regards to talcum powder and its role in</p> <p>21 ovarian cancer. As far as my discussions or</p> <p>22 presentations around the role of inflammation in</p> <p>23 cancer, including ovarian, it -- it is -- it is</p> <p>24 possible, but I can't think of a specific</p>
<p style="text-align: right;">Page 91</p> <p>1 subsequent to that, participated in at least one</p> <p>2 review for the Department of Defense in reviewing</p> <p>3 ovarian cancer research grants. So that is --</p> <p>4 And then my membership in the</p> <p>5 Vanderbilt Cancer Center as well as the</p> <p>6 University of Alabama Birmingham Comprehensive</p> <p>7 Cancer Center certainly have been involved in a</p> <p>8 number of projects across a diversity of cancer</p> <p>9 types, including ovarian and breast cancer.</p> <p>10 Q Prior to being hired by the plaintiffs'</p> <p>11 lawyers in this litigation, you had not</p> <p>12 investigated the potential mechanisms by which</p> <p>13 talcum powder could cause ovarian cancer. Is</p> <p>14 that fair?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form.</p> <p>17 A Specific -- as in terms of a specific</p> <p>18 fundamental research project?</p> <p>19 MS. BROWN:</p> <p>20 Q At all.</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form.</p> <p>23 A So my research has included the role of</p> <p>24 inflammation and a number of biological processes</p>	<p style="text-align: right;">Page 93</p> <p>1 presentation.</p> <p>2 MS. BROWN:</p> <p>3 Q Okay. Since you've been hired by</p> <p>4 plaintiffs' lawyers, you have done some research</p> <p>5 into the potential role of inflammation and</p> <p>6 ovarian cancer. Is that right?</p> <p>7 MS. O'DELL:</p> <p>8 Object to the form.</p> <p>9 A Since -- since my -- what was requested</p> <p>10 of me from the plaintiffs' attorneys was to</p> <p>11 provide a review of the biological plausibility</p> <p>12 and a connection between talcum powder and</p> <p>13 inflammation and then discuss the relationship</p> <p>14 between inflammation and cancer.</p> <p>15 MS. BROWN:</p> <p>16 Q Okay. As I understand you, Dr. Levy,</p> <p>17 you were asked by the plaintiffs' lawyers to</p> <p>18 provide a review of the literature as it relates</p> <p>19 to the biological plausibility of talcum powder</p> <p>20 and ovarian cancer. Is that right?</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form.</p> <p>23 A No, that's not correct. What I was --</p> <p>24 I was asked to provide an opin- -- expert opinion</p>

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<p>1 on the biological plausibility of the mechanism</p> <p>2 that -- of the ability of exposure of talc and</p> <p>3 its constituent components to cause inflammation</p> <p>4 and/or cancer.</p> <p>5 MS. BROWN:</p> <p>6 Q Do you see those as two different</p> <p>7 things?</p> <p>8 A Yes.</p> <p>9 Q Okay. So you were asked to provide a</p> <p>10 mechanism by which talcum powder could cause</p> <p>11 cancer?</p> <p>12 A No, that's not correct.</p> <p>13 MS. O'DELL:</p> <p>14 Objection to form.</p> <p>15 MS. BROWN:</p> <p>16 Q Okay. Explain it to me.</p> <p>17 A I -- I was asked to provide a -- an</p> <p>18 opinion on the biological plausibility --</p> <p>19 Q Of talcum powder causing cancer?</p> <p>20 A -- of talcum powder leading to the</p> <p>21 biological changes necessary to cause cancer.</p> <p>22 Q Okay. As I understand what you just</p> <p>23 said, you were asked to re- -- to provide an</p> <p>24 opinion on the biological plausibility of talcum</p>	<p>1 some neurological diseases.</p> <p>2 So this was a similar review as -- of</p> <p>3 those topics when asked to examine the biological</p> <p>4 plausibility of a cause and effect; in this case,</p> <p>5 cause being exposure to talcum powder and effect</p> <p>6 being progression to cancer.</p> <p>7 Q Prior to being hired by the plaintiffs'</p> <p>8 lawyers, you had not considered the biological</p> <p>9 plausibility of talcum powder causing ovarian</p> <p>10 cancer. Correct?</p> <p>11 A No. I would say that's not true in</p> <p>12 isolation. And the reason I say that's not true</p> <p>13 is I had been aware of some of the literature and</p> <p>14 certainly some of the press that surrounded the</p> <p>15 suspected associations between talcum powder</p> <p>16 exposure and cancer. So I was familiar with the</p> <p>17 concept, but I had not at the time, until hired</p> <p>18 by the plaintiffs' attorney, spent a significant</p> <p>19 amount of time reviewing the literature and</p> <p>20 developing a written opinion as to that</p> <p>21 biological plausibility.</p> <p>22 Q You have not published your opinion</p> <p>23 contained in -- your opinions contained in the</p> <p>24 report that we marked as Exhibit 2. Is that</p>
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<p>1 powder leading to biologic changes that are</p> <p>2 needed to cause cancer. Is that fair?</p> <p>3 MS. O'DELL:</p> <p>4 Object to the form.</p> <p>5 A So I was asked from -- by the attorneys</p> <p>6 to review the available literature across the</p> <p>7 spectrum of cancer and talcum powder and</p> <p>8 constituent literature to develop an opinion</p> <p>9 around the biological plausibility that exposure</p> <p>10 of -- exposure to talcum powder is</p> <p>11 biologically -- that there is a biologically</p> <p>12 plausible mechanism that that can cause cancer.</p> <p>13 MS. BROWN:</p> <p>14 Q Okay. And that is not something that</p> <p>15 you had done prior to being hired by the</p> <p>16 plaintiffs' lawyers. Fair?</p> <p>17 A Developing such an opinion?</p> <p>18 Q Correct.</p> <p>19 A Or -- or -- so writing such a report,</p> <p>20 no, that is not something I -- I had done prior</p> <p>21 to -- to this. My research has been primarily in</p> <p>22 data integration and the examination of</p> <p>23 mechanistic effects in cancer, rare disease,</p> <p>24 and -- and in diabetes specifically, as well as</p>	<p>1 correct?</p> <p>2 A That is correct.</p> <p>3 Q You have not presented the opinions</p> <p>4 contained in Exhibit 2 at any medical or</p> <p>5 scientific conference; correct?</p> <p>6 A That's correct.</p> <p>7 Q You have not disclosed the opinions</p> <p>8 contained in Exhibit 2 to any of your colleagues;</p> <p>9 correct?</p> <p>10 MS. O'DELL:</p> <p>11 Object to the form.</p> <p>12 A Not at this time, no. Considering I</p> <p>13 had -- I had just finalized the report a short</p> <p>14 time ago, I haven't had the opportunity to</p> <p>15 consider publication, presentation, or -- or</p> <p>16 discussion with colleagues.</p> <p>17 MS. BROWN:</p> <p>18 Q Do you plan to seek publication of the</p> <p>19 information contained in your report in Exhibit</p> <p>20 2?</p> <p>21 A I -- I haven't made a determination at</p> <p>22 this time. It's been a fascinating area to</p> <p>23 research. Certainly there's -- that would</p> <p>24 certainly be a future possibility.</p>

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<p style="text-align: right;">Page 98</p> <p>1 Q Does HudsonAlpha --</p> <p>2 First of all, what's your position at</p> <p>3 HudsonAlpha, Doctor?</p> <p>4 A So I'm a faculty investigator, which</p> <p>5 would be analogous to a faculty member at a</p> <p>6 research institution, similar to -- or I should</p> <p>7 take a step back and just --</p> <p>8 To be accurate, HudsonAlpha is a</p> <p>9 private nonprofit research institution, similar</p> <p>10 to Broad Institute, Stowers, et cetera. So we</p> <p>11 are academic in nature, meaning that most of our</p> <p>12 funding or the vast majority of our funding comes</p> <p>13 from grants and contracts. So that's why I say</p> <p>14 it's analogous to faculty at a research</p> <p>15 institution.</p> <p>16 My other responsibilities are the</p> <p>17 management and oversight of the production and</p> <p>18 research laboratories, so that provides us an</p> <p>19 opportunity to work with approximately 1200</p> <p>20 different laboratories from around the world in</p> <p>21 support of roughly 5,000 projects over the last</p> <p>22 nine and a half years. And that's -- it's</p> <p>23 provided a broad spectrum of activities and</p> <p>24 abilities to work in these types of projects.</p>	<p style="text-align: right;">Page 100</p> <p>1 or -- or -- or dispute whether or not those</p> <p>2 ovarian cancer or other cancer types may have had</p> <p>3 a relationship to talcum powder. So the short</p> <p>4 answer being I -- I don't have the information to</p> <p>5 answer that.</p> <p>6 MS. BROWN:</p> <p>7 Q HudsonAlpha has a Code of Ethics. Are</p> <p>8 you familiar with it?</p> <p>9 A Yes.</p> <p>10 Q Are you familiar with the financial</p> <p>11 disclosure requirements of HudsonAlpha?</p> <p>12 A I am.</p> <p>13 Q Have you complied with those in</p> <p>14 connection with your work as an expert witness</p> <p>15 for plaintiffs in this case?</p> <p>16 A I have.</p> <p>17 Q And tell us what you've done to comply</p> <p>18 with HudsonAlpha's Code of Ethics and financial</p> <p>19 disclosure requirements.</p> <p>20 A Their Code of Ethics and financial</p> <p>21 requirement is requirement to disclose any</p> <p>22 relationships that have a financial component</p> <p>23 over -- I don't recall the minimum amount, but it</p> <p>24 is -- it is fairly modest, hundreds of dollars.</p>
<p style="text-align: right;">Page 99</p> <p>1 And then I also oversee the clinical</p> <p>2 laboratories as well. And adult oncology is a</p> <p>3 major focus of that research. I currently lead</p> <p>4 the largest profiling effort in adult cancer in</p> <p>5 the nation, which involves 15 national cancer</p> <p>6 institutes. And ovarian cancer is a component of</p> <p>7 that research, although not the only cancer that</p> <p>8 we research in that -- in that's -- in that</p> <p>9 program.</p> <p>10 Q None of the 5,000 projects you just</p> <p>11 mentioned have dealt with talc. Is that fair?</p> <p>12 A That is fair.</p> <p>13 Q And none of the work at the clinical</p> <p>14 labs that you just mentioned have dealt with</p> <p>15 talc; correct?</p> <p>16 MS. O'DELL:</p> <p>17 Object.</p> <p>18 A I am -- I would say there's a</p> <p>19 statistical probability that some of the ovarian</p> <p>20 cancer samples that have been observed in the</p> <p>21 clinical laboratory may very well have</p> <p>22 been -- have come from patients exposed to talcum</p> <p>23 powder. But I have no direct knowledge of that,</p> <p>24 nor have we performed any testing to confirm</p>	<p style="text-align: right;">Page 101</p> <p>1 And that reporting requirement is the -- is -- is</p> <p>2 for the previous year, and it is due in July, I</p> <p>3 believe is the time frame, although I'd have to</p> <p>4 make sure. It's -- I know it's not the end of</p> <p>5 the calendar year. So on my next disclosure,</p> <p>6 this, of course, activity would be disclosed.</p> <p>7 In addition to that, via</p> <p>8 conversation -- regular review with the president</p> <p>9 of the institution, I provide a general report on</p> <p>10 consulting activities; for example, these</p> <p>11 activities.</p> <p>12 HudsonAlpha's policy is faculty members</p> <p>13 are allowed up to 20 percent of your time towards</p> <p>14 consulting activities that have a relationship to</p> <p>15 your research area, such as the evaluation of the</p> <p>16 biologically plausible mechanism of talc in</p> <p>17 ovarian cancer. So based on both the timing of</p> <p>18 the Code of Ethics with regards to the financial</p> <p>19 disclosure as well as the ad hoc reporting of</p> <p>20 consulting engagements with the president of the</p> <p>21 institution, I'm in compliance with the current</p> <p>22 policies of HudsonAlpha.</p> <p>23 Q The president of HudsonAlpha is aware</p> <p>24 of your opinions in this case?</p>

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<p style="text-align: right;">Page 102</p> <p>1 A I have not discussed my opinions</p> <p>2 specifically to this case with him; just the</p> <p>3 general knowledge that I was asked to participate</p> <p>4 as an expert witness. He didn't ask, and I</p> <p>5 didn't provide the content.</p> <p>6 Q No one at HudsonAlpha is aware of your</p> <p>7 opinion that talcum powder causes chronic</p> <p>8 inflammation which can cause ovarian cancer? Is</p> <p>9 that right?</p> <p>10 A I have -- I have not specifically</p> <p>11 shared the contents of the report or -- or my</p> <p>12 opinions widely at HudsonAlpha.</p> <p>13 Q Did you disclose last July that you had</p> <p>14 already been hired and submitted invoices to the</p> <p>15 plaintiffs' lawyers?</p> <p>16 A I'm sure I did.</p> <p>17 Q Do you have that documentation?</p> <p>18 A No. It's -- it's an electronic</p> <p>19 disclosure. It's not actually done on paper.</p> <p>20 Q One of the things that HudsonAlpha does</p> <p>21 is it partners with the University of Alabama in</p> <p>22 a comprehensive cancer center; correct?</p> <p>23 A No, that wouldn't be correct.</p> <p>24 HudsonAlpha is very specific --</p>	<p style="text-align: right;">Page 104</p> <p>1 members on both institutions.</p> <p>2 MS. BROWN:</p> <p>3 Q Fair to say, then, Doctor, you have not</p> <p>4 participated in any work with the University of</p> <p>5 Alabama's Comprehensive Cancer Center?</p> <p>6 MS. O'DELL:</p> <p>7 Object to the form.</p> <p>8 A No, that's not true.</p> <p>9 MS. BROWN:</p> <p>10 Q Have you worked with the University of</p> <p>11 Alabama's Comprehensive Cancer Center on projects</p> <p>12 involving ovarian cancer?</p> <p>13 MS. O'DELL:</p> <p>14 Objection. Asked and answered.</p> <p>15 A I would -- I would have to review the</p> <p>16 specific projects that we've -- we've done to</p> <p>17 answer that.</p> <p>18 As the codirector of a core facility</p> <p>19 for the University of Alabama Comprehensive</p> <p>20 Cancer Center, it is likely that we've worked on</p> <p>21 some projects related to ovarian cancer, but I</p> <p>22 can't specifically name them. They are -- I</p> <p>23 would -- I would characterize them as infrequent.</p> <p>24 MS. BROWN:</p>
<p style="text-align: right;">Page 103</p> <p>1 And you may be more familiar with this</p> <p>2 than I.</p> <p>3 They're very specific with their use of</p> <p>4 the word "partnership" and they're, in fact, very</p> <p>5 specific that they do not engage in a -- anything</p> <p>6 titled "a partnership." So they -- I would not</p> <p>7 characterize them as a partner of the University</p> <p>8 of Alabama Cancer Center.</p> <p>9 We certainly have -- there are faculty</p> <p>10 members at University of Alabama Birmingham who</p> <p>11 are -- have adjunct appointments at HudsonAlpha,</p> <p>12 just as I have appointments at University of</p> <p>13 Alabama Birmingham and I am a member of their</p> <p>14 cancer center.</p> <p>15 Q Are you aware of the work that</p> <p>16 HudsonAlpha does with the University of Alabama's</p> <p>17 Comprehensive Cancer Center?</p> <p>18 MS. O'DELL:</p> <p>19 Object to the form. Asked and</p> <p>20 answered.</p> <p>21 A I'm aware of some of the work, but I --</p> <p>22 certainly I -- I don't -- I don't necessarily</p> <p>23 have knowledge of the full spectrum of those</p> <p>24 projects, given that they involve many faculty</p>	<p style="text-align: right;">Page 105</p> <p>1 Q Have any of those projects attempted to</p> <p>2 research the potential causes of ovarian cancer?</p> <p>3 A Again, I'd have -- I'd have to review</p> <p>4 the projects. They're certainly --</p> <p>5 fundamentally, most of the questions regarding</p> <p>6 the analysis of cancer samples are routinely to</p> <p>7 investigate their cause or their treatment. So I</p> <p>8 would -- I would answer that question as highly</p> <p>9 likely.</p> <p>10 Q Would you agree the cause of ovarian</p> <p>11 cancer remains unknown today?</p> <p>12 MS. O'DELL:</p> <p>13 Object to the form.</p> <p>14 A No, I would -- I would -- I would not</p> <p>15 agree that it -- I would not agree to that</p> <p>16 general statement.</p> <p>17 MS. BROWN:</p> <p>18 Q What are the causes of ovarian cancer</p> <p>19 in your mind, Doctor?</p> <p>20 A Well, the -- the causes of -- of</p> <p>21 a -- of any number of cancers, including ovarian</p> <p>22 cancer, are probably more well understood now</p> <p>23 than ever, and their complexities I think now are</p> <p>24 just beginning to be appreciated in the sense</p>

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<p style="text-align: right;">Page 106</p> <p>1 that cancer is a disease of unregulated cell 2 growth. 3 Back to our earlier con- -- earlier 4 conversation, some of the fundamental facts that 5 we had discussed and, in fact, I think well 6 replicated in a number of sources, as you pointed 7 out to me, you know, illustrate that there's a 8 milieu of genetic change leading to cellular 9 transformation, and that cellular damage, if we 10 consolidate that as cellular damage, then has to 11 work in concert with a number of other events 12 providing the right environment for a tumor to 13 grow, such as inflammation, chronic or acute. 14 And, so, the -- you know, the -- the -- you know, 15 giving a singular cause would be inappropriate. 16 But I would say the mechanistic causes 17 of cancer are reasonably well understood, but how 18 those apply to the wide diversity of cancer types 19 remains an area of active investigation. 20 I think what's interesting on cancer in 21 general is that there's no -- really no longer a 22 bucket diagnosis. It is -- it -- lung cancer is 23 more complex than lung cancer and ovarian cancer, 24 certainly with the --</p>	<p style="text-align: right;">Page 108</p> <p>1 Now, the -- whether that represents the 2 complete milieu of possibilities is -- is what is 3 currently under research. 4 MS. BROWN: 5 Q Were you aware that the University of 6 Alabama Comprehensive Cancer Center is an NCI 7 center, National Cancer Institute? 8 A Yes. It's -- it's not only an 9 NCI-designated center; it's an NCI-designated 10 comprehensive cancer center, which is a slightly 11 different classification. It's a -- there's more 12 criteria for a cancer center to meet to become 13 comprehensive. 14 Q What does it mean to be an NCI center, 15 to you, if you know? 16 A Stated very simply, it means you have 17 a -- your cancer center is funded by a support 18 grant directly from the National Cancer Institute 19 to provide -- that supports not only patient care 20 but also supports basic research, epidemiology 21 and -- and health outcomes research in cancer. 22 So, in a nutshell, it is a fairly 23 comprehensive grant that supports a wide variety 24 of work within a cancer center that extends</p>
<p style="text-align: right;">Page 107</p> <p>1 As I'm sure you're well aware, with the 2 molecular subtypes and other things, it's a 3 complicated disease as well. 4 So to summarize that is -- to summarize 5 all of that complexity by saying that the cause 6 is known or unknown I think would vastly 7 underestimate the -- our current state of the art 8 or knowledge of how complex cancer is as a 9 condition. 10 Q Sure. 11 Scientists, researchers, public health 12 authorities continue to investigate the mechanism 13 by which ovarian cancer is caused. Correct? 14 A That's correct. 15 Q We do not, sitting here today in 2019, 16 have a complete understanding of the etiology of 17 ovarian cancer. Correct? 18 MS. O'DELL: 19 Object to the form. 20 A I would say we have substantial 21 knowledge of factors and exposures that either 22 predispose or directly cause cancer in a large 23 number of -- large number of cancer areas, 24 including ovarian cancer.</p>	<p style="text-align: right;">Page 109</p> <p>1 beyond basic -- basic care. 2 Q The National Cancer Institute has 3 funded a number of projects that the scientists 4 at HudsonAlpha are working on. Is that fair? 5 A I'd have to certainly review the grant 6 portfolio. But I'm certain that, since I myself 7 have funding from that cancer center, yes, the 8 NCI does fund some -- some number of 9 investigators at HudsonAlpha. 10 Q And you consider the NCI to be a 11 reputable public health authority; correct? 12 A No, not necessarily. The NCI is really 13 not a public health authority. The N -- the NCI 14 is a -- is a scientific administration center 15 within the National Institutes of Health. 16 Now, I'm speaking of their extramural 17 programs. The NCI also have intramural programs, 18 where they have their own researchers and their 19 own projects. I'm less familiar with those 20 activities. 21 But together, I would state that the 22 NCI is a -- I don't have -- I guess I have not 23 had any experience with the NCI that would lead 24 me to say that they are an authoritative public</p>

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<p style="text-align: right;">Page 110</p> <p>1 health authority.</p> <p>2 Q Before forming your opinions in this</p> <p>3 case, Dr. Levy, did you look to see what the NCI</p> <p>4 states about whether talcum powder causes ovarian</p> <p>5 cancer?</p> <p>6 A I believe I did see, from a number of</p> <p>7 statements, certainly potentially from the NCI,</p> <p>8 regarding the complete opinion and -- and</p> <p>9 knowledge base for the role of talcum powder in</p> <p>10 ovarian cancer.</p> <p>11 Q Do you recall that the NCI has</p> <p>12 concluded that there's inadequate evidence that</p> <p>13 talcum powder increases the risk of ovarian</p> <p>14 cancer?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form.</p> <p>17 A Which -- what specifically are you</p> <p>18 referring to? I -- I wouldn't be able to answer</p> <p>19 that accurately without knowing which specific</p> <p>20 report or statement that you're referring to.</p> <p>21 MS. BROWN:</p> <p>22 Q I'm wondering if, sitting here today,</p> <p>23 you recall looking at information about the</p> <p>24 classification of risk factors for ovarian cancer</p>	<p style="text-align: right;">Page 112</p> <p>1 you are prepared to offer the opinion that talcum</p> <p>2 powder causes ovarian cancer.</p> <p>3 A I don't -- I don't think we have the</p> <p>4 complete information for a sing- -- you know, to</p> <p>5 have the opinion of a singular cause. But, at</p> <p>6 the same time, my opinions are that, as stated in</p> <p>7 the report, there's a clear and well-evidenced</p> <p>8 biologically plausible role for talcum powder</p> <p>9 leading to ovarian cancer.</p> <p>10 Q On page 2 of your report, the second</p> <p>11 full paragraph that begins "My report</p> <p>12 consists" --</p> <p>13 You with me?</p> <p>14 A Yes.</p> <p>15 Q -- you state -- you reference your</p> <p>16 conclusions regarding this cause-and-effect</p> <p>17 relationship.</p> <p>18 Do you see that?</p> <p>19 A I do.</p> <p>20 Q Do you mean by that that you have an</p> <p>21 opinion that talcum powder causes the effect of</p> <p>22 ovarian cancer?</p> <p>23 A No. That -- that wasn't the meaning of</p> <p>24 that statement of cause and effect. It was -- it</p>
<p style="text-align: right;">Page 111</p> <p>1 as done by the NCI.</p> <p>2 A I don't recall that specifically. I</p> <p>3 don't also recall seeing any statements from the</p> <p>4 NCI regarding safety of any product.</p> <p>5 Q In forming your opinions in this case,</p> <p>6 Dr. Levy, did you consider the conclusions of</p> <p>7 public health authorities like the FDA, the NCI,</p> <p>8 NIH as it relates to talcum powder in ovarian</p> <p>9 cancer?</p> <p>10 A So I certainly considered information</p> <p>11 from each of those entities. But I would make a</p> <p>12 statement I don't -- I don't recall from any of</p> <p>13 those entities seeing a single conclusion.</p> <p>14 Q Is it your opinion, Dr. Levy, that</p> <p>15 talcum powder causes ovarian cancer?</p> <p>16 A I wasn't asked to provide an opinion if</p> <p>17 talcum powder causes cancer. I was -- I was</p> <p>18 asked to develop an opinion as to the biological</p> <p>19 plausibility of -- of talcum powder leading</p> <p>20 to -- leading to change.</p> <p>21 Now, that's what I was asked from the</p> <p>22 attorneys. If you're asking -- are you asking me</p> <p>23 what my opinion is --</p> <p>24 Q Well, I want to know if, in this case,</p>	<p style="text-align: right;">Page 113</p> <p>1 was a -- more of a general statement of a cause</p> <p>2 being exposure to talc and effect being that</p> <p>3 biologically plausible mechanism.</p> <p>4 Q You mentioned a moment ago that you</p> <p>5 don't think we have the complete info on a</p> <p>6 singular cause of ovarian cancer. Is that right?</p> <p>7 MS. O'DELL:</p> <p>8 Objection to form.</p> <p>9 A Sorry. Let me read your question</p> <p>10 again.</p> <p>11 I have -- I have not seen any evidence</p> <p>12 that suggests that there is a singular cause of</p> <p>13 ovarian cancer.</p> <p>14 MS. BROWN:</p> <p>15 Q You have not seen sufficient evidence</p> <p>16 to suggest that talcum powder could be one of the</p> <p>17 causes of ovarian cancer; correct?</p> <p>18 MS. O'DELL:</p> <p>19 Object to the form.</p> <p>20 A I would disagree. As -- as stated,</p> <p>21 the -- I have not seen evidence that there's a</p> <p>22 singular cause of ovarian cancer. I think there</p> <p>23 is ample evidence that there are a multitude of</p> <p>24 mechanisms that you can get cellular damage and</p>

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<p>1 cellular change within the ovary which then leads</p> <p>2 to malignant transformation, and that, as stated</p> <p>3 in the report, there's a biologically plausible</p> <p>4 mechanism that exposure to talcum powder and its</p> <p>5 constituents can create those necessary changes.</p> <p>6 MS. BROWN:</p> <p>7 Q Do you believe, Doctor, there's</p> <p>8 sufficient evidence that talcum powder, through</p> <p>9 chronic inflammation, causes ovarian cancer in</p> <p>10 some individuals?</p> <p>11 A No. That -- that was not my -- not my</p> <p>12 opinion or statement. And I would say</p> <p>13 specifically chronic inflammation is, again,</p> <p>14 narrowing the focus in an inappropriate way, and</p> <p>15 the evidence doesn't illustrate that chronic</p> <p>16 inflammation is a singular sufficient detail or,</p> <p>17 I should say, effect to result in ovarian cancer.</p> <p>18 It's certainly a factor, as -- as well described</p> <p>19 in the -- in the literature.</p> <p>20 And -- and, again, I would defer to</p> <p>21 other expert reports that have similar opinions</p> <p>22 regarding inflammation, chronic inflammation</p> <p>23 being one of them.</p> <p>24 And it may be important to provide an</p>	<p>1 of observations and studies that</p> <p>2 have -- certainly exist. And, again, their</p> <p>3 review and -- and content is what went to the</p> <p>4 opinions in my report.</p> <p>5 Q And most of the studies that you cite,</p> <p>6 Dr. Levy, talking about chronic inflammation</p> <p>7 refer to chronic inflammation as a hypothesis of</p> <p>8 one of the ways cancer might form in the ovary.</p> <p>9 Correct?</p> <p>10 MS. O'DELL:</p> <p>11 Object to the form.</p> <p>12 A Let me -- sorry. Let me read your</p> <p>13 question.</p> <p>14 No. I would disagree. At least,</p> <p>15 certainly not most of the studies that I cite.</p> <p>16 MS. BROWN:</p> <p>17 Q Do you believe chronic inflammation is</p> <p>18 an established mechanism of ovarian cancer?</p> <p>19 A Yes, in the sense that chronic</p> <p>20 inflammation is a well-established mechanism of</p> <p>21 cancer in general, including ovarian cancer.</p> <p>22 This is first observed in the 1800s and has since</p> <p>23 been -- become well-established in the -- in the</p> <p>24 cancer field that inflammation plays a</p>
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<p>1 important distinction that cellular damage or</p> <p>2 what we can refer to as acute inflammation can</p> <p>3 cause -- certainly has been shown and is</p> <p>4 well-evidenced that it causes -- can lead to</p> <p>5 molecular changes that can lead to cancer.</p> <p>6 Chronic inflammation is a slightly --</p> <p>7 is in a slightly different biological perspective</p> <p>8 in that it provides the correct environment for</p> <p>9 those cancerous changes to take hold and allow</p> <p>10 malignant transformation, as I mentioned.</p> <p>11 So I -- I do view them as working in</p> <p>12 concert but not necessarily independent. So when</p> <p>13 you ask a question that specifically narrows it</p> <p>14 to chronic inflammation or even acute</p> <p>15 inflammation in a singular fashion, you know, my</p> <p>16 answers will largely be the same, that that's, in</p> <p>17 and of itself, is too limited to describe as a</p> <p>18 specific cause, singular or otherwise, of ovarian</p> <p>19 cancer or of cancer in general.</p> <p>20 Q You'd agree that the research regarding</p> <p>21 whether chronic inflammation can cause ovarian</p> <p>22 cancer is ongoing?</p> <p>23 A Yes, I would agree it is -- it is</p> <p>24 ongoing research. But there are a large number</p>	<p>1 significant role in both the initiation as well</p> <p>2 as progression of cancer.</p> <p>3 Q What methodology did you employ for</p> <p>4 coming to the opinion that chronic inflammation</p> <p>5 is a well-established cause of ovarian cancer?</p> <p>6 A Just general mechanism in terms of</p> <p>7 evaluating biological plausibility.</p> <p>8 Q I understand, Dr. Levy, you have a</p> <p>9 general opinion that chronic inflammation can</p> <p>10 lead to some cancer. Is that right?</p> <p>11 MS. O'DELL:</p> <p>12 Objection to form. Misstates his</p> <p>13 testimony.</p> <p>14 A I -- I have an opinion regarding the</p> <p>15 role and importance of inflammation in the</p> <p>16 initiation and progression of cancer.</p> <p>17 MS. BROWN:</p> <p>18 Q And, as it relates to ovarian cancer,</p> <p>19 what methodology did you employ to arrive at your</p> <p>20 conclusion that chronic inflammation is an</p> <p>21 established cause of ovarian cancer?</p> <p>22 A I -- I did not arrive at that specific</p> <p>23 conclusion, nor was I asked to.</p> <p>24 Q You do not believe that chronic</p>

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<p style="text-align: right;">Page 118</p> <p>1 inflammation has been established as a cause of</p> <p>2 ovarian cancer; correct?</p> <p>3 MS. O'DELL:</p> <p>4 Object to the form.</p> <p>5 A No, that -- that's not what I said.</p> <p>6 MS. BROWN:</p> <p>7 Q Explain it to me.</p> <p>8 A I've stated that chronic inflammation</p> <p>9 or inflammation in general, including chronic and</p> <p>10 acute infor -- inflammation, is a component and a</p> <p>11 necessary component for the initiation and</p> <p>12 progression of -- of cancer as we understand it</p> <p>13 today. And, in that, cancer, certainly ovarian</p> <p>14 cancer as well as a variety of other cancer</p> <p>15 types, is included.</p> <p>16 Q What methodology did you employ to</p> <p>17 arrive at the conclusion that ovarian cancer is</p> <p>18 one of the cancers that can be caused by chronic</p> <p>19 inflammation?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form. Misstates his</p> <p>22 testimony.</p> <p>23 A Yeah. Again, we're not -- I'm not</p> <p>24 making a specific causal opinion with respect to</p>	<p style="text-align: right;">Page 120</p> <p>1 from animal models to in vitro studies, in vivo</p> <p>2 studies, cohort studies, case-control studies.</p> <p>3 There was quite a broad spectrum of information</p> <p>4 across a large number of years.</p> <p>5 Q Do you believe you reviewed the</p> <p>6 totality of the epidemiology on talcum powder use</p> <p>7 and ovarian cancer?</p> <p>8 MS. O'DELL:</p> <p>9 Object to the form.</p> <p>10 A I -- I reviewed the available studies</p> <p>11 that appeared to be relevant for the -- for the</p> <p>12 opinions that are expressed in my report.</p> <p>13 MS. BROWN:</p> <p>14 Q And when you say "available," what do</p> <p>15 you mean?</p> <p>16 A Meaning that I could -- I could</p> <p>17 discover in the scientific literature.</p> <p>18 Q Did you conduct your own literature</p> <p>19 searches in connection with your work in this</p> <p>20 case?</p> <p>21 A I did.</p> <p>22 Q How did you go about finding the</p> <p>23 totality of the evidence relating to whether</p> <p>24 talcum powder causes ovarian cancer?</p>
<p style="text-align: right;">Page 119</p> <p>1 any -- whether -- whether inflammation, talcum</p> <p>2 powder use or other exposures. I -- my -- my</p> <p>3 opinion in the report is -- is -- was not asked</p> <p>4 to be a causal opinion.</p> <p>5 MS. BROWN:</p> <p>6 Q You reference on page 2 of your report</p> <p>7 that your opinions are based on assessing and</p> <p>8 weighing the totality of the evidence, including</p> <p>9 relevant literature and available documentation</p> <p>10 and your experience as a geneticist and</p> <p>11 scientific researcher. Do you see that?</p> <p>12 A Yes.</p> <p>13 Q What do you mean by "the totality of</p> <p>14 the evidence"?</p> <p>15 A All of the evidence available at the</p> <p>16 time that I was researching this report.</p> <p>17 Q All of the evidence concerning what?</p> <p>18 A Concerning a variety of subjects</p> <p>19 surrounding ovarian cancer, talcum powder use,</p> <p>20 and then inflammation and related subjects as my</p> <p>21 literature review and review of available</p> <p>22 information progressed.</p> <p>23 So there was a, I guess, a large number</p> <p>24 of tangential directions that -- that I examined,</p>	<p style="text-align: right;">Page 121</p> <p>1 A So the -- my methodology for the</p> <p>2 literature review in establishing my opinion</p> <p>3 regarding the biological plausibility of talcum</p> <p>4 powder exposure inflammation and its potential</p> <p>5 role in ovarian cancer was based on, you know, my</p> <p>6 activities and many other literature searches, so</p> <p>7 using a variety of computational tools and -- and</p> <p>8 web-based resources, from journals to, I would</p> <p>9 say, primarily PubMed being a resource, but also</p> <p>10 ISI, Web of Science, Google Scholar and a variety</p> <p>11 of -- bioRxiv and I'm sure a number of other</p> <p>12 sources. But those were probably the more</p> <p>13 primary resources for establishing what</p> <p>14 literature was available.</p> <p>15 Q Did you ask the plaintiffs' lawyers for</p> <p>16 any scientific literature that you used in</p> <p>17 forming your opinions in this case?</p> <p>18 A What do you mean by "ask"? There</p> <p>19 is -- as far as did I ask for their similar</p> <p>20 process, no.</p> <p>21 There were some papers that I had</p> <p>22 identified but was not able to access the full</p> <p>23 content via the libraries that I have access to.</p> <p>24 So in some of those cases, specific references</p>

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<p>1 that I provided, those full -- that full content</p> <p>2 was provided by the plaintiffs' lawyer to allow</p> <p>3 me to review it.</p> <p>4 Q Did the plaintiffs' lawyers give you a</p> <p>5 set of epidemiology on which you're relying on to</p> <p>6 form your opinion?</p> <p>7 A No, they did not.</p> <p>8 Q If I look at your report, I see a</p> <p>9 reference list and then a separate Exhibit B. Is</p> <p>10 that right?</p> <p>11 A Yes.</p> <p>12 Q So, for example, on page 18 of your</p> <p>13 report, you have a list of literature cited.</p> <p>14 Correct?</p> <p>15 A Yes.</p> <p>16 Let me make sure I have the page</p> <p>17 correct.</p> <p>18 Yes, beginning on page 18.</p> <p>19 Q Is everything that appears in the</p> <p>20 literature-cited list something that you found on</p> <p>21 your own, Dr. Levy?</p> <p>22 A I would have to review the -- the list.</p> <p>23 But there are certainly --</p> <p>24 Let me --</p>	<p>1 relying on information in that article to form</p> <p>2 your opinions in this case?</p> <p>3 A No. I'm not relying on any singular</p> <p>4 article or source to form my opinion on the case.</p> <p>5 Q Are you relying in part on the</p> <p>6 information contained in the Blount article?</p> <p>7 A Since I include it in the cited</p> <p>8 literature, certainly in some -- in some part.</p> <p>9 Q What information are you relying on in</p> <p>10 the Blount article?</p> <p>11 A I would have to review the article to</p> <p>12 remind myself where the --</p> <p>13 Q Take a look at it. We'll pull it right</p> <p>14 now.</p> <p>15 What about Paoletti on page 22? Was</p> <p>16 that something you found on your own or did the</p> <p>17 lawyers give you that?</p> <p>18 A So Paoletti --</p> <p>19 Q Uh-huh.</p> <p>20 A Page 22?</p> <p>21 Q Uh-huh.</p> <p>22 A Actually, the Paoletti one is familiar.</p> <p>23 That's an interesting one because it's in</p> <p>24 Italian.</p>
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<p>1 I believe the Saed abstracts, as an</p> <p>2 example --</p> <p>3 Let me see if there are --</p> <p>4 No. I -- I believe, in the literature</p> <p>5 cited, there are certainly some number of</p> <p>6 examples of information that was provided during</p> <p>7 the course of the development of my report from</p> <p>8 the plaintiffs' attorneys in terms of literature</p> <p>9 for my consideration, but that in no case -- in</p> <p>10 every case it was provided as a -- as</p> <p>11 information.</p> <p>12 The vast majority or nearly the</p> <p>13 totality of this was information that I had --</p> <p>14 that I indeed discovered myself and shared with</p> <p>15 the -- the attorneys, but certainly not complete.</p> <p>16 Q On page 18 you cite an article by</p> <p>17 Blount.</p> <p>18 Do you see that?</p> <p>19 A Yes.</p> <p>20 Q Was that given to you by the</p> <p>21 plaintiffs' lawyers?</p> <p>22 A I'd have to look at my records. I</p> <p>23 don't recall.</p> <p>24 Q Off of the top of your head, are you</p>	<p>1 Q Are you relying on the information in</p> <p>2 the Paoletti article to form your opinions in the</p> <p>3 case?</p> <p>4 A Again, the -- I wasn't relying on any</p> <p>5 singular article but instead tried to present and</p> <p>6 provide reference to as comprehensive a</p> <p>7 collection of relevant literature in this -- in</p> <p>8 this space as possible, of which Paoletti,</p> <p>9 although being in Italian, there were some --</p> <p>10 enough translated aspects of that that it was</p> <p>11 worthy to include in the -- in that cited</p> <p>12 literature as being relevant to the -- to</p> <p>13 those -- to those opinions.</p> <p>14 Q Just to make sure we get on the same</p> <p>15 page here, Dr. Levy, when I ask are you relying</p> <p>16 on something, I don't mean by that question to</p> <p>17 suggest it's the only thing you're relying on.</p> <p>18 And I'll try to say "in part" to make it easy for</p> <p>19 us. Okay?</p> <p>20 A Right. Just want to be -- make sure</p> <p>21 we're clear.</p> <p>22 Q Absolutely. So do I.</p> <p>23 And I want to know are you relying in</p> <p>24 part on anything in the Paoletti article to form</p>

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<p style="text-align: right;">Page 126</p> <p>1 your opinions in this case?</p> <p>2 A I would say in -- in part. As far as</p> <p>3 my opinions regarding the biologically plausible</p> <p>4 mechanism that was presented, no, it does not</p> <p>5 rely on that specific conclusions of that paper</p> <p>6 but, rather, that paper was included because of</p> <p>7 its results regarding asbestos contamination in</p> <p>8 industrial talc, which only support -- add</p> <p>9 support to the mechanism that I presented in the</p> <p>10 report.</p> <p>11 Q Is your opinion in this case, Doctor,</p> <p>12 based on an assumption that baby powder contains</p> <p>13 asbestos?</p> <p>14 A No, it is not.</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form.</p> <p>17 MS. BROWN:</p> <p>18 Q Is your opinion in this case based on</p> <p>19 an assumption that baby powder contains</p> <p>20 fragrances?</p> <p>21 MS. O'DELL:</p> <p>22 Objection to form.</p> <p>23 A My -- my opinion considers the totality</p> <p>24 of the constituent components of baby powder,</p>	<p style="text-align: right;">Page 128</p> <p>1 presented.</p> <p>2 MS. BROWN:</p> <p>3 Q Do you believe that baby talc alone can</p> <p>4 cause inflammation that may lead to ovarian</p> <p>5 cancer?</p> <p>6 A Based on my review of the literature,</p> <p>7 there are a number of studies, both of those</p> <p>8 involving human studies in terms of case</p> <p>9 controls, as well as a number of animal studies</p> <p>10 and then, more specifically, in vitro studies</p> <p>11 that look at talcum powder and its ability to</p> <p>12 produce clear markers of inflammation.</p> <p>13 I am -- the -- I am not aware of any</p> <p>14 specific testing that looked at platy talc</p> <p>15 individually as a singular component without</p> <p>16 the -- or out of the context of the products we</p> <p>17 were just describing in a similar analysis. So I</p> <p>18 don't -- I don't know that answer.</p> <p>19 Q Is it your opinion that</p> <p>20 Johnson & Johnson baby powder products are</p> <p>21 contaminated with asbestos?</p> <p>22 MS. O'DELL:</p> <p>23 Object to the form. Asked and</p> <p>24 answered.</p>
<p style="text-align: right;">Page 127</p> <p>1 Shower to Shower, you know, under -- either, as</p> <p>2 we've been referring to it simply as talc or</p> <p>3 talcum powder or by trade names such as</p> <p>4 Johnson & Johnson or Shower to Shower, so the --</p> <p>5 my opinions, as stated in the report, being</p> <p>6 reasonably -- or trying to be reasonably</p> <p>7 comprehensive. Therefore, it's not, you know,</p> <p>8 limited to any -- any singular component, whether</p> <p>9 it be majority or minority, in the -- in the</p> <p>10 talcum powder products, as I just stated.</p> <p>11 MS. BROWN:</p> <p>12 Q Is your opinion in this case based on</p> <p>13 an assumption that Johnson & Johnson baby powder</p> <p>14 products contain heavy metals?</p> <p>15 MS. O'DELL:</p> <p>16 Objection to form.</p> <p>17 A Again, similar to the earlier</p> <p>18 statement, the opinion is not subject to</p> <p>19 any -- any singular component. I think the</p> <p>20 information regarding the -- in deferring to some</p> <p>21 of the other experts regarding the knowledge of</p> <p>22 constituent components, whether they be heavy</p> <p>23 metals or asbestos, only helps to support the</p> <p>24 biological plausibility of the mechanism I</p>	<p style="text-align: right;">Page 129</p> <p>1 A I -- I -- I have -- I have been</p> <p>2 provided expert report, and some of those are</p> <p>3 referenced in the -- in the report, as we were</p> <p>4 describing, that describe testing of a number</p> <p>5 of -- number of samples,</p> <p>6 included -- Johnson & Johnson included in that,</p> <p>7 that showed how they -- that the results of those</p> <p>8 reports showed contamination by asbestos or --</p> <p>9 or -- or asbestos-like fiber. So, therefore,</p> <p>10 I've been presented with that evidence.</p> <p>11 MS. BROWN:</p> <p>12 Q Have you relied on that evidence in</p> <p>13 forming your opinions in this case?</p> <p>14 A Again, no, not -- not as a singular</p> <p>15 evidence. So, as we just discussed a moment ago,</p> <p>16 that is a component piece of evidence that</p> <p>17 leads -- and is supportive of the biologically</p> <p>18 plausible mechanism described in the report.</p> <p>19 You know, certainly, it is inarguable</p> <p>20 that asbestos and asbestos-like fibers cause</p> <p>21 inflammation. There's also ample evidence of the</p> <p>22 inflammatory effects of talc. And -- and talc</p> <p>23 pleurodesis, for example, is -- is designed to</p> <p>24 produce inflammatory response as a treatment.</p>

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<p>1 So I think, again, similar to the</p> <p>2 relationship of asbestos and inflammation, it's a</p> <p>3 well-established scientific fact that talc has an</p> <p>4 inflammatory role now. Or I should say as of</p> <p>5 today.</p> <p>6 Q Have you attempted to quantify, based</p> <p>7 on the reports of Dr. Longo that you reviewed,</p> <p>8 how much asbestos contamination is in</p> <p>9 Johnson & Johnson baby powder products?</p> <p>10 MS. O'DELL:</p> <p>11 Objection. Vague as to form.</p> <p>12 A I --</p> <p>13 MS. O'DELL:</p> <p>14 As to the volume and time contained,</p> <p>15 et cetera.</p> <p>16 A My -- my answer is simply that I wasn't</p> <p>17 asked to quantify that as part of my report.</p> <p>18 MS. BROWN:</p> <p>19 Q Whether there is asbestos in Johnson &</p> <p>20 Johnson baby powder products or not does not</p> <p>21 impact your opinions in this case; is that right?</p> <p>22 MS. O'DELL:</p> <p>23 Object to the form.</p> <p>24 A The opinions regarding the biological</p>	<p>1 in any of the above-referenced studies.</p> <p>2 MS. O'DELL:</p> <p>3 Objection. Misstates his testimony.</p> <p>4 A So reading -- reading back my</p> <p>5 testimony --</p> <p>6 MS. BROWN:</p> <p>7 Q So, Doctor, I see that you're looking</p> <p>8 at the realtime?</p> <p>9 A Yes.</p> <p>10 Q To get clarification on the question?</p> <p>11 A No. To -- to remem- -- to -- you asked</p> <p>12 me a question about my statement.</p> <p>13 Q Correct.</p> <p>14 A And I was reviewing specifically what I</p> <p>15 had stated so I could answer your question</p> <p>16 accurately.</p> <p>17 Q Terrific. So I want to know what you</p> <p>18 were talking about when you said you were unable</p> <p>19 to discover the contamination rate.</p> <p>20 A To clarify, I was not asked to estimate</p> <p>21 or determine the contamination rate, and my</p> <p>22 statement regarding that was in reference to the</p> <p>23 material I reviewed and the literature that is</p> <p>24 referenced in my report. I don't recall in any</p>
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<p>1 plausibility described in my report and its</p> <p>2 relationship to asbestos are somewhat separate,</p> <p>3 meaning that I have -- I was not able to discover</p> <p>4 what the contamination rate or content of</p> <p>5 asbestos was in any of the referenced studies</p> <p>6 through the course of my report, so, therefore, I</p> <p>7 can't comment on the likelihood or -- of -- of</p> <p>8 how many or any -- or any or all of those samples</p> <p>9 contain asbestos.</p> <p>10 MS. BROWN:</p> <p>11 Q And sounds like you did some work</p> <p>12 attempting to see if you could calculate a</p> <p>13 contamination rate. Is that what you were</p> <p>14 describing?</p> <p>15 MS. O'DELL:</p> <p>16 Object -- object to the form.</p> <p>17 Misstates his testimony.</p> <p>18 A No. No, not at all. I stated that I</p> <p>19 didn't have information available to assess</p> <p>20 either -- either way.</p> <p>21 MS. BROWN:</p> <p>22 Q Tell me what you meant when you</p> <p>23 testified that you were not able to discover what</p> <p>24 the contamination rate or content of asbestos was</p>	<p>1 of those studies observing a specific statement</p> <p>2 of amount of asbestos in the talcum powder</p> <p>3 products that were under study. So, therefore, I</p> <p>4 am not able to form an opinion surrounding that</p> <p>5 contamination rate.</p> <p>6 Q Would the same be true, Doctor, for</p> <p>7 heavy metals?</p> <p>8 A Yes, that's correct.</p> <p>9 Q And when I say the same would be true,</p> <p>10 that means you were not able to calculate a rate</p> <p>11 of heavy metal contamination of any of the talcum</p> <p>12 powder products in the studies you reviewed?</p> <p>13 MS. O'DELL:</p> <p>14 Objection. Vague.</p> <p>15 A I was not asked to.</p> <p>16 MS. BROWN:</p> <p>17 Q Did you attempt to quantify the amount</p> <p>18 of heavy metals?</p> <p>19 MS. O'DELL:</p> <p>20 Objection.</p> <p>21 A I certainly reviewed the literature to</p> <p>22 understand what information was available</p> <p>23 regarding the products that may have been used</p> <p>24 and what testing may have been done on</p>

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<p>1 those -- on those products.</p> <p>2 MS. BROWN:</p> <p>3 Q And, as it relates to fragrances, have</p> <p>4 you calculated the amount of fragrances that are</p> <p>5 present in Johnson & Johnson's baby powder</p> <p>6 products?</p> <p>7 MS. O'DELL:</p> <p>8 Objection to form.</p> <p>9 A I -- I wasn't asked to -- to make those</p> <p>10 calculations. And I would defer to other expert</p> <p>11 reports that I had an opportunity to review</p> <p>12 recently that did perform those calculations.</p> <p>13 MS. BROWN:</p> <p>14 Q Your opinions in this case are not</p> <p>15 dependent on whether or not --</p> <p>16 A I think that was --</p> <p>17 Q -- there are fragrances in</p> <p>18 Johnson & Johnson's baby powder; correct?</p> <p>19 MS. O'DELL:</p> <p>20 Objection.</p> <p>21 A Sorry. Let me read that.</p> <p>22 Sorry. Could you rephrase your</p> <p>23 question? The question that appears on the</p> <p>24 monitor is that there are fragrances in</p>	<p>1 fragrances as well as asbestos, I would say my</p> <p>2 opinion now is that that information continues to</p> <p>3 support the biologically plausible mechanism</p> <p>4 presented in my report.</p> <p>5 MS. BROWN:</p> <p>6 Q Your opinion that chronic inflammation</p> <p>7 is a biologically plausible mechanism by which</p> <p>8 talcum powder could cause ovarian cancer is not</p> <p>9 dependent on heavy metals being present in talcum</p> <p>10 powder; correct?</p> <p>11 MS. O'DELL:</p> <p>12 Object to the form. Asked and</p> <p>13 answered.</p> <p>14 A My -- my opinions are not based on --</p> <p>15 on any singular component or constituent because</p> <p>16 the -- the available information did not</p> <p>17 scientifically test any singular components</p> <p>18 or -- or allow --</p> <p>19 I'm not aware of any studies that</p> <p>20 examine the inflammatory or other effects of</p> <p>21 talcum powder that contained heavy metals versus</p> <p>22 did not.</p> <p>23 MS. BROWN:</p> <p>24 Q So, for purposes of your opinions in</p>
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<p>1 Johnson & Johnson baby powder, question mark.</p> <p>2 MS. BROWN:</p> <p>3 Q That's why it's tricky when you read</p> <p>4 the realtime. Just listen to my question. It'll</p> <p>5 be more helpful.</p> <p>6 Your opinion in this case is not</p> <p>7 dependent on whether or not there are fragrances</p> <p>8 in Johnson & Johnson baby powder. Correct?</p> <p>9 MS. O'DELL:</p> <p>10 Excuse me. Objection to form.</p> <p>11 You may refer to realtime any time you</p> <p>12 want to, Doctor.</p> <p>13 But I object to the form of the</p> <p>14 question.</p> <p>15 A So my -- my -- I was -- what was</p> <p>16 requested of me, again, stating for clarity, was</p> <p>17 to describe a biologically plausible mechanism</p> <p>18 for talc and all of its constituent components</p> <p>19 having a role in inflammation and progression to</p> <p>20 ovarian cancer based on -- on the information at</p> <p>21 hand.</p> <p>22 Certainly the fact, as we've been</p> <p>23 provided later, the ex- -- the recent review of</p> <p>24 some other expert reports regarding the</p>	<p>1 this case, for your piece of the puzzle, so to</p> <p>2 speak, it is not important to you whether or not</p> <p>3 there are heavy metals in baby powder; correct?</p> <p>4 MS. O'DELL:</p> <p>5 Objection to form. Asked and answered.</p> <p>6 A No, that's not correct. I would say</p> <p>7 the presence of all of the constituent components</p> <p>8 is very important for -- from the -- from the</p> <p>9 perspective of that biologically plausible</p> <p>10 mechanism, and that includes the type of talc,</p> <p>11 the structure of the talc, you know, its -- any</p> <p>12 potential contaminants that are there, as well as</p> <p>13 the complete spectrum of other constituent</p> <p>14 components, fragrances, heavy metals.</p> <p>15 And, of course, fragrances have their</p> <p>16 own milieu of constituent components that, again,</p> <p>17 I was not asked to comment on or describe in</p> <p>18 detail but certainly are part of the overall</p> <p>19 studies.</p> <p>20 MS. BROWN:</p> <p>21 Q You have a conclusion in your report on</p> <p>22 page 17, Doctor, conclusion number 2, that talcum</p> <p>23 powder products cause chronic inflammation.</p> <p>24 Do you see that?</p>

35 (Pages 134 to 137)

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<p>1 A Yes.</p> <p>2 And I would -- and then my conclu- --</p> <p>3 Q Hold on. No question yet.</p> <p>4 A Okay.</p> <p>5 Q And what I want to know, Doctor, is how</p> <p>6 do you define the talcum powder products that</p> <p>7 you've listed here on page 17 of your report?</p> <p>8 A Primarily the products that are -- when</p> <p>9 I consider the totality of everything that I've</p> <p>10 been examining, the talcum powder products,</p> <p>11 including Johnson & Johnson and Shower to Shower</p> <p>12 as, you know, I refer to those consumer products</p> <p>13 under the term "talcum powder."</p> <p>14 Q What about other consumer talcum powder</p> <p>15 products? Are they included in your conclusions</p> <p>16 here on page 17?</p> <p>17 MS. O'DELL:</p> <p>18 Object to the form.</p> <p>19 A So my -- my conclusions are based on</p> <p>20 the -- on the literature review. And, similar to</p> <p>21 our discussions regarding contaminants and the</p> <p>22 ability to quantitate those, many of the studies</p> <p>23 did not specifically delineate which product or</p> <p>24 the timing of that product.</p>	<p>1 don't know if any of the studies used -- used</p> <p>2 that. I'd have to, again, would have to review</p> <p>3 some of that information to determine if there</p> <p>4 was a -- if that was a variable in any of the</p> <p>5 given studies that are the basis of the report.</p> <p>6 Q What methodology did you employ here in</p> <p>7 coming to your conclusion that chronic</p> <p>8 inflammation is caused by talcum powder products?</p> <p>9 MS. O'DELL:</p> <p>10 Objection. Asked and answered.</p> <p>11 A Yeah. Again, to restate, similar to</p> <p>12 the earlier questions, the -- my methodology was</p> <p>13 based on standard methodology for establishing</p> <p>14 biological plausibility, which is a, in a</p> <p>15 summary, a review of the totality of the evidence</p> <p>16 and then a summary of that to establish if, based</p> <p>17 on established or -- or known or factual</p> <p>18 principles, is there a -- can -- can a mechanism</p> <p>19 described go from cause to effect in a -- again,</p> <p>20 in an evidence-supported biologically plausible</p> <p>21 manner.</p> <p>22 There's a few references I can provide</p> <p>23 you that describe that method in a published</p> <p>24 manner, if that's helpful.</p>
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<p>1 In contrast, some of the more recent</p> <p>2 information available specific to the</p> <p>3 constituents did meet that definition, so I would</p> <p>4 say these conclusions apply to both the specific</p> <p>5 products that I mentioned, Johnson & Johnson and</p> <p>6 Shower to Shower, as well as potentially other</p> <p>7 products. But quant- -- quantifying which study,</p> <p>8 I would have to go through study by study to</p> <p>9 answer any questions about which specific may be</p> <p>10 included.</p> <p>11 MS. BROWN:</p> <p>12 Q Do you include talc-containing</p> <p>13 deodorizing sprays in your definition of a talcum</p> <p>14 powder product?</p> <p>15 A None of the literature that -- that I</p> <p>16 reviewed or can recall was limited to those</p> <p>17 deodorant sprays in terms of a -- as a study</p> <p>18 variable that I can -- that I can think of.</p> <p>19 Q I'm not sure what you mean by that.</p> <p>20 A So the -- the basis of this report was</p> <p>21 on the talcum powder products, and I don't recall</p> <p>22 any of the studies that delineated talcum powder</p> <p>23 as a powder versus a talc-containing deodorant</p> <p>24 spray as a -- as a variable in the study. So I</p>	<p>1 MS. BROWN:</p> <p>2 Q That would be helpful.</p> <p>3 A They are -- these are our --</p> <p>4 MS. O'DELL:</p> <p>5 These are mine.</p> <p>6 THE WITNESS:</p> <p>7 Yeah.</p> <p>8 There's a -- I can get them --</p> <p>9 MS. BROWN:</p> <p>10 Q Are the published methods referenced in</p> <p>11 your report, Doctor?</p> <p>12 A No, actually, those are not.</p> <p>13 Q Okay. How would you go about finding</p> <p>14 the published methods that contain a description</p> <p>15 of the methodology you employed in this case?</p> <p>16 A No. It's that I was just saying that</p> <p>17 there's a published -- peer-reviewed published</p> <p>18 article that is the same as the method I used, if</p> <p>19 you -- if you wanted to review that. I didn't</p> <p>20 reference this specific paper in the report.</p> <p>21 Q Okay. And you have a -- do you have a</p> <p>22 copy of that in front of you right now, Doctor?</p> <p>23 A I do.</p> <p>24 Q Okay. So let's mark that as Exhibit</p>

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<p style="text-align: right;">Page 142</p> <p>1 14. 2 (DEPOSITION EXHIBIT NUMBER 14 3 WAS MARKED FOR IDENTIFICATION.) 4 MS. BROWN: 5 Q The title of the document is 6 "Evaluating Biological Plausibility in Supporting 7 Evidence For Action Through Systematic Reviews in 8 Public Health." 9 When is the first time you reviewed 10 this document, Doctor? 11 A In the last -- the last day or so. 12 Q Was the document provided to you by the 13 lawyers for plaintiffs? 14 A Yes. 15 Q The document is not referenced in your 16 report. True? 17 A It is not referenced. That's correct. 18 Q You did not review the document prior 19 to writing your report; correct? 20 A That's right. 21 Q The document was something the lawyers 22 for plaintiffs gave you after you had already 23 written and authored your report; correct? 24 A That's correct. I provided that as an</p>	<p style="text-align: right;">Page 144</p> <p>1 MS. O'DELL: 2 Object to the form. 3 A No, that's not true. 4 MS. BROWN: 5 Q The lawyers for plaintiffs found 6 Exhibit 14 in the scientific literature; correct? 7 A That's correct. 8 Q In reviewing the scientific literature, 9 did you pay attention to the articles that 10 classify different types of talcum powder 11 products? 12 MS. O'DELL: 13 Object to the form. 14 A Could you give a specific example, and 15 then I -- 16 I wouldn't be able to answer without 17 knowing. 18 MS. O'DELL: 19 Q Sure. 20 Do you understand that some of the talc 21 epidemiology separates use by type of talcum 22 powder product? 23 MS. O'DELL: 24 Objection to form.</p>
<p style="text-align: right;">Page 143</p> <p>1 example of the -- of a published example of the 2 methodology that I employed. 3 Q You didn't endeavor to research the 4 scientific literature to find a published -- 5 published example of your methodology, did you? 6 MS. O'DELL: 7 Objection to form. 8 A I -- it wasn't -- that wasn't what I 9 was -- I wasn't asked to reference the 10 methodology in my report. I was, again, asked to 11 provide an opinion on a biologically plausible 12 mechanism and then, since our discussion has 13 transferred to methodology, to be complete, I 14 wanted to provide an example of a published 15 version of the methodology that -- that is 16 similar to or at least describes in a summary or 17 really in that particular paper an exemplary 18 fashion of the criteria for biological 19 plausibility and the methods used therein. 20 MS. BROWN: 21 Q Exhibit 14 is the product of research 22 the lawyers for plaintiffs conducted on a 23 published article regarding your methodology. 24 True?</p>	<p style="text-align: right;">Page 145</p> <p>1 A Again, do you have a specific example 2 of one of the studies so I could -- so I'd be 3 able to accurately answer your question? 4 MS. BROWN: 5 Q Here's what I want to know. Did you 6 look at the studies that separated deodorizing 7 sprays from powder products from cornstarch, for 8 example? 9 A Certainly in my review I made as 10 comprehensive a review of available literature 11 as -- as possible. And, again, if you can name a 12 specific study or one of the references, I can 13 confirm if that was -- if that was part of 14 the -- my review of the epidemiology. 15 Q Do you hold the opinion that talcum 16 powder-containing deodorant sprays causes 17 inflammation? 18 MS. O'DELL: 19 Objection to form. Vague. 20 A So if the -- 21 Again, I was asked to provide an 22 opinion on the biologically plausible mechanism 23 regarding talc and talcum powder. So, 24 presumably, any product that contains talcum</p>

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<p style="text-align: right;">Page 146</p> <p>1 powder could possibly follow that same</p> <p>2 biologically plausible mechanism.</p> <p>3 MS. BROWN:</p> <p>4 Q Is there a certain amount of talcum</p> <p>5 powder that a product must contain to cause</p> <p>6 inflammation?</p> <p>7 MS. O'DELL:</p> <p>8 Objection to form.</p> <p>9 A That wasn't something I was asked</p> <p>10 to -- to quantify, similar to the discussions we</p> <p>11 had about metals, fragrances, and asbestos.</p> <p>12 MS. BROWN:</p> <p>13 Q In forming your opinion that talcum</p> <p>14 powder products cause inflammation, you have not</p> <p>15 attempted to quantify how much talcum powder is</p> <p>16 in those products; is that right?</p> <p>17 MS. O'DELL:</p> <p>18 Objection to form. Asked and answered.</p> <p>19 A So my -- my review included a number of</p> <p>20 studies that looked at exposure rates, and my</p> <p>21 review also included the review of some studies</p> <p>22 that did not include use frequency as well as use</p> <p>23 duration. And, so, both of those considerations</p> <p>24 in terms of my review of the epidemiology were</p>	<p style="text-align: right;">Page 148</p> <p>1 Objection to form. Vague.</p> <p>2 A My -- my opinions are based on the</p> <p>3 available scientific literature regarding the</p> <p>4 testing performed on talcum powder and talcum</p> <p>5 powder products.</p> <p>6 I -- in my review of those results, I</p> <p>7 did not see a specific enumeration of any one</p> <p>8 particular chemical composition that was -- had a</p> <p>9 greater or lesser cause or effect relationship.</p> <p>10 MS. BROWN:</p> <p>11 Q Do you know how much talcum powder is</p> <p>12 in the Shower to Shower product?</p> <p>13 A No. I wasn't -- I wasn't asked to</p> <p>14 quantify that, and I would defer to some of the</p> <p>15 other expert reports regarding the composition of</p> <p>16 those products.</p> <p>17 Q Do you include cornstarch as a talcum</p> <p>18 powder product?</p> <p>19 MS. O'DELL:</p> <p>20 Object to the form.</p> <p>21 A Cornstarch was included in some of the</p> <p>22 epidemiology studies, as you -- as you mentioned</p> <p>23 a moment ago.</p> <p>24 MS. BROWN:</p>
<p style="text-align: right;">Page 147</p> <p>1 undertaken, but I did not attempt to quantify</p> <p>2 those relationships specifically.</p> <p>3 MS. BROWN:</p> <p>4 Q Okay. So there's two different issues</p> <p>5 there that I want to ask you about. One, I want</p> <p>6 to talk to you about whether the talcum powder</p> <p>7 products you've described on page 17 of your</p> <p>8 report have a specific composition, in your mind.</p> <p>9 Okay?</p> <p>10 Two, I want to talk to you about what</p> <p>11 you were just answering, which is is there a</p> <p>12 specific amount of the product that you believe</p> <p>13 causes inflammation.</p> <p>14 Do you understand the difference?</p> <p>15 A I do.</p> <p>16 MS. O'DELL:</p> <p>17 Objection to form.</p> <p>18 MS. BROWN:</p> <p>19 Q Okay. So let's start, one, with the</p> <p>20 product. In forming the opinion that talcum</p> <p>21 powder products cause inflammation, is there a</p> <p>22 particular chemical composition that you are</p> <p>23 relying on?</p> <p>24 MS. O'DELL:</p>	<p style="text-align: right;">Page 149</p> <p>1 Q Do you consider cornstarch to be a</p> <p>2 talcum powder product that also causes</p> <p>3 inflammation?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form.</p> <p>6 A My -- my review of the literature</p> <p>7 doesn't -- I'm thinking through the available</p> <p>8 studies, and I don't recall which studies that</p> <p>9 may -- may have been a dependent variable in</p> <p>10 terms of the determination. So I -- I can't</p> <p>11 answer that. I -- I don't have the information</p> <p>12 to answer that accurately.</p> <p>13 MS. BROWN:</p> <p>14 Q So, sitting here today, you're not sure</p> <p>15 if cornstarch would be a talcum powder product</p> <p>16 that causes inflammation as you described on page</p> <p>17 17?</p> <p>18 MS. O'DELL:</p> <p>19 Objection.</p> <p>20 A No. So --</p> <p>21 MS. O'DELL:</p> <p>22 Misstates the testimony.</p> <p>23 But you may answer if you understand</p> <p>24 the question.</p>

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<p style="text-align: right;">Page 150</p> <p>1 A So corn -- cornstarch and -- and talcum 2 powder are -- are -- when I'm referring to talcum 3 powder and talcum powder products, cornstarch, as 4 a singular component -- or singular product, is 5 not included in that definition. 6 Now, whether products that contain talc 7 also contain cornstarch, I -- I'm not able to 8 say. 9 MS. BROWN: 10 Q Right. And so that's my question. 11 What about a product like Shower to Shower that 12 contains talc and cornstarch? How have 13 you -- what methodology have you employed to 14 arrive at the conclusion that the Shower to 15 Shower product causes inflammation? 16 MS. O'DELL: 17 Object to the form. 18 A So my -- what I was requested was to 19 write an opinion as to the, again, the 20 biologically plausible mechanism that exposure to 21 talc and its constituents can lead to 22 inflammation. 23 I wasn't asked to provide as to what 24 the minimum or maximum thresholds are of any</p>	<p style="text-align: right;">Page 152</p> <p>1 on knowledge of how much talcum powder is 2 actually in the product; correct? 3 MS. O'DELL: 4 Objection. Misstates his testimony. 5 A Again, not a -- it wasn't part of -- it 6 wasn't an opinion I was asked to provide. 7 The -- the only -- or, I should say, 8 a -- a study that looked at the -- summarizing 9 the epidemiology literature that I reviewed, some 10 of those studies had a duration and component as 11 far as general talcum powder and talcum powder 12 product use. 13 MS. BROWN: 14 Q And I want to -- 15 A I don't -- 16 MS. O'DELL: 17 Excuse me. Let him finish. 18 A I was -- I was going to say I don't 19 recall those quantitating the percentage of 20 talcum powder in a -- in a given product in the 21 study. 22 MS. BROWN: 23 Q Right. And, so, you're getting a 24 little into the second question, which I do want</p>
<p style="text-align: right;">Page 151</p> <p>1 product or of any component of that product or 2 constituent. 3 The information I was provided was the 4 analysis of products like Shower to Shower and 5 Johnson & Johnson's product, to evaluate the 6 spectrum of talc and asbestos contamination in 7 some of the constituent components, and then -- 8 and, therefore, develop an opinion as to 9 the -- whether or not that those products are 10 supported by the same mechanism that I developed 11 the opinion on, meaning they have the constituent 12 components to cause inflammation. 13 MS. BROWN: 14 Q You have not made a determination of a 15 particular amount of talcum powder that is 16 required to be in a product for it to cause 17 chronic inflammation; correct? 18 MS. O'DELL: 19 Object to the form. 20 A I wasn't asked to provide such an 21 opinion. 22 MS. BROWN: 23 Q Your opinion that talcum powder 24 products cause chronic inflammation is not based</p>	<p style="text-align: right;">Page 153</p> <p>1 to talk about, which is how much people are 2 exposed to. 3 But sticking with just what's in the 4 product, have you made a determination that there 5 is a threshold amount of talcum powder that is 6 required to be in a product before you can 7 conclude that that product will cause chronic 8 inflammation? 9 MS. O'DELL: 10 Objection to form. Asked and answered. 11 A I -- again, I wasn't asked to provide 12 that -- that threshold opinion. 13 MS. BROWN: 14 Q And understanding whether or not there 15 is a threshold of how much talcum powder has to 16 be in a product to cause inflammation is not 17 necessary for you to opine that talcum powder 18 products cause chronic inflammation? 19 MS. O'DELL: 20 Objection. Misstates his testimony. 21 A So my -- my use of the terminology 22 "talcum powder products" includes the product and 23 all of its constituent components, which would 24 be, as we earlier discussed, talcum powder,</p>

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<p style="text-align: right;">Page 154</p> <p>1 fragrances, and any contaminating substances, 2 such as asbestos or -- or heavy metals. 3 And, so, therefore, to -- to more -- to 4 answer -- to be able to answer your question 5 accurately, we would -- I think we would have to 6 have some discussions as to the type of talcum 7 powder and the level of exposure to be able to 8 answer that regarding my opinion in terms of 9 level. 10 You know, the -- to clarify, the -- 11 during this research and the -- and having the 12 opportunity to review much of the literature in 13 talcum powder, it's a -- it's a fascinating field 14 because it is similar to asbestos. It appears 15 that the diversity of products and the diversity 16 of talc sources are like having a thorn bush with 17 different size thorns, and, depending on the 18 constituent components, you know, those thorns 19 are bigger or smaller or otherwise. And -- but 20 my opinion is based on the fact that the presence 21 of any of those thorns is sufficient to cause 22 some inflammatory response. 23 MS. BROWN: 24 Q Does a talcum powder product with 10</p>	<p style="text-align: right;">Page 156</p> <p>1 exposure to inflammation to the initiation of 2 core progression of cancer. And that's -- that's 3 been the focus of my opinion. 4 MS. BROWN: 5 Q Have you attempted to quantify talc 6 exposure as it relates to individuals? 7 A No, I have not. 8 Again, my -- my opinions are primarily 9 limited to the -- to the biological mechanism. 10 Q Well, isn't that dependent, though, on 11 how much talc a person is exposed to? 12 MS. O'DELL: 13 Objection. 14 A No. Again, separating the -- so the 15 question of the mechanism is -- 16 Can an exposure result in a mechanism 17 is separate from how much of an exposure is 18 required to cause that mechanism. 19 MS. BROWN: 20 Q So you've identified two questions for 21 us. One, can exposure result in a mechanism. 22 Correct? 23 A (Nods affirmatively.) 24 Q And, two, how much of an exposure do</p>
<p style="text-align: right;">Page 155</p> <p>1 percent talc cause chronic inflammation, in your 2 view? 3 MS. O'DELL: 4 Object to the form. Incomplete 5 hypothetical. 6 A I -- I don't have the information to 7 answer that. 8 MS. BROWN: 9 Q Does a talcum powder product with 10 50 percent talc cause chronic inflammation, in 11 your view? 12 A Again, I don't have the information to 13 answer that. 14 MS. O'DELL: 15 Object to the form. 16 MS. BROWN: 17 Q Is it necessary for you to determine 18 the level of talc in a product before determining 19 that it can cause chronic inflammation? 20 MS. O'DELL: 21 Objection. Asked and answered. 22 A No. My -- my -- so my opinion was 23 asked to answer the question of can -- is there a 24 biologically plausible mechanism from talc</p>	<p style="text-align: right;">Page 157</p> <p>1 you need to produce a mechanism. Correct? 2 MS. O'DELL: 3 Objection to form. 4 A Correct. 5 MS. BROWN: 6 Q And, in this case, you have answered 7 question number one, can exposure to talc cause 8 chronic inflammation. Correct? 9 A So my -- yeah. My -- my report details 10 the -- that opinion regarding a biologically 11 plausible mechanism. 12 Q You have not, in this case, answered 13 question number two, which is how much exposure 14 to talc is needed to cause chronic inflammation. 15 Is that right? 16 MS. O'DELL: 17 Objection to form. 18 A I wasn't asked to provide such a 19 mechanism or such a -- such an opinion. 20 Part of my review included some of the 21 epidemiology studies that examine that question, 22 but I certainly would defer to the -- the number 23 of -- of epidemiologists who are -- who are 24 providing testimony in this case, rather than try</p>

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<p style="text-align: right;">Page 158</p> <p>1 and paraphrase or opine on their work. 2 MS. BROWN: 3 Q Do you believe -- 4 MS. O'DELL: 5 Excuse me. We've been going about an 6 hour and 15 minutes. I'd love to take a break in 7 the next two or three minutes and -- 8 MS. BROWN: 9 It will probably take me a little 10 longer than that, but I'm mindful of the time, 11 and I'll just finish this subject and take a 12 break -- 13 MS. O'DELL: 14 Well, Dr. Levy, would you like a break 15 now? 16 THE WITNESS: 17 I think we can finish this subject. 18 MS. BROWN: 19 Thank you. 20 THE WITNESS: 21 I -- I'd rather conclude it than break 22 it up. 23 MS. BROWN: 24 Q So, Doctor, as it relates to how much</p>	<p style="text-align: right;">Page 160</p> <p>1 epidemiology studies found that conclusion and, 2 as -- as reviewed in the report, you know, found 3 an increased risk with increasing -- increasing 4 exposure appears, with the current knowledge in 5 the literature, to increase risk. But my opinion 6 was not to further quantify or further describe 7 that. 8 MS. BROWN: 9 Q Many of the studies you looked at did 10 not show a dose response; correct? 11 MS. O'DELL: 12 Objection to form. 13 A The limitation of several of the 14 studies I reviewed was that they did not examine 15 a dose response, so that, therefore, the study 16 was unable -- unable to make that conclusion 17 because they didn't look. 18 MS. BROWN: 19 Q And some of the studies that did 20 attempt to look at duration and/or frequency did 21 not show a linear dose response. Correct? 22 A I would have to look at the specific 23 studies. But in -- in summary, studies that did 24 look at dose response, particularly more recent</p>
<p style="text-align: right;">Page 159</p> <p>1 talc is needed to cause inflammation that can 2 cause cancer, that wasn't what you were asked to 3 figure out in this case. Is that right? 4 MS. O'DELL: 5 Objection to form. 6 A No. Well, I -- I was -- I was asked to 7 provide a review of the literature in terms of 8 talc exposure and inflammation and, in that 9 review, identified a number of studies that 10 examined some relationships to dose. 11 But I -- as you -- as you see in my 12 conclusions, none of them speak to dose or 13 duration in terms of that -- of that mechanism. 14 MS. BROWN: 15 Q You are not offering an opinion in this 16 case, Doctor, that perineal use of talcum powder 17 exposes an individual to enough talc to cause 18 chronic inflammation than can cause cancer; 19 correct? 20 MS. O'DELL: 21 Objection to form. 22 A My review of studies that attempted to 23 answer that specific question found a -- or a 24 number of studies, both -- or a number of</p>	<p style="text-align: right;">Page 161</p> <p>1 studies with larger numbers of participants, the 2 meta-analysis studies, found a significant 3 relationship between duration of use as well as 4 frequency of use in terms of their -- their risk 5 ratios. 6 Q And you are not going to offer the 7 opinion in this case that a woman using Johnson's 8 Baby Powder products perineally is exposed to 9 enough talcum powder to cause chronic 10 inflammation that can cause cancer. True? 11 MS. O'DELL: 12 Object to the form. 13 A I -- I wasn't asked to -- to provide 14 that opinion. 15 MS. BROWN: 16 Q And so, as such, you haven't attempted 17 to quantify how much talcum powder, as used 18 perineally, might get to the ovary. Is that 19 fair? 20 A Again, wasn't -- wasn't asked. I was 21 able to review some of the literature that 22 is -- appears to be long -- longstanding, well 23 established over the last greater than 40 years 24 that show a clear -- and I believe the FDA</p>

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<p style="text-align: right;">Page 162</p> <p>1 statement is -- is describing it as inarguable --</p> <p>2 that talc can migrate either from perineal</p> <p>3 exposure or even from inhalation exposure and be</p> <p>4 found in the ovary.</p> <p>5 A quantitation of how much exposure is</p> <p>6 required for that migration to occur and -- or</p> <p>7 how many times of exposure that migration needs</p> <p>8 to occur, I think it's been a fairly wide</p> <p>9 diversity of -- of studies on that subject.</p> <p>10 And, so, based on that, I'm not able to</p> <p>11 offer an opinion as to a minimal or maximum dose</p> <p>12 required to get there, other than -- but,</p> <p>13 instead, state that there is enough evidence to</p> <p>14 say factually that migration through the -- or</p> <p>15 through at least two mechanisms of exposure, talc</p> <p>16 can be found in the ovary. And I would suggest</p> <p>17 that -- or I'm not aware of any study that</p> <p>18 quantitates that further.</p> <p>19 Q Is it essential to your opinion that</p> <p>20 talc causes chronic inflammation that can lead to</p> <p>21 ovarian cancer that some amount of talc be</p> <p>22 present in the actual ovary?</p> <p>23 MS. O'DELL:</p> <p>24 Object to the form.</p>	<p style="text-align: right;">Page 164</p> <p>1 talc has to reach the ovary for the chronic</p> <p>2 inflammation to occur. Is that right?</p> <p>3 MS. O'DELL:</p> <p>4 Objection.</p> <p>5 A Not -- specific to your question,</p> <p>6 chronic inflammation, no, not necessarily.</p> <p>7 MS. BROWN:</p> <p>8 Q Is it your opinion in this case,</p> <p>9 Doctor, that a woman can develop ovarian cancer</p> <p>10 from chronic inflammation from talc without any</p> <p>11 particle of talc ever reaching the ovary?</p> <p>12 MS. O'DELL:</p> <p>13 Objection to form.</p> <p>14 A No, I didn't -- I -- I certainly did</p> <p>15 not make that statement. And the --</p> <p>16 Again, restating the -- this summary of</p> <p>17 my -- my opinion, that the biologically plausible</p> <p>18 mechanism for talc exposure to inflammation to</p> <p>19 cellular damage and then potentially creating the</p> <p>20 correct environment is based on evidence showing</p> <p>21 talc exposure in the ovary.</p> <p>22 MS. BROWN:</p> <p>23 Q Okay. So critical to your opinion,</p> <p>24 then, some talc has to get to the ovary at some</p>
<p style="text-align: right;">Page 163</p> <p>1 A So my -- my -- my opinion regarding the</p> <p>2 biologically plausible mechanism, again, does not</p> <p>3 rely on duration of exposure or amount of</p> <p>4 exposure.</p> <p>5 So, therefore, I would -- I would</p> <p>6 answer your question directly that it would be</p> <p>7 no, it does not -- it would not necessarily</p> <p>8 require talc to be present at the ovary at any</p> <p>9 given time point for there to be the potential</p> <p>10 that she had some inflammatory injury due to talc</p> <p>11 exposure at a previous time.</p> <p>12 That would, of course, be two different</p> <p>13 questions, one being effect of exposure and</p> <p>14 second question being is there clearance of that</p> <p>15 exposure over time if use is discontinued.</p> <p>16 So that's, again, two different -- two</p> <p>17 very different scientific studies would be --</p> <p>18 would be necessary.</p> <p>19 MS. BROWN:</p> <p>20 Q And you have not undertaken either of</p> <p>21 those studies. Is that fair?</p> <p>22 A That's fair.</p> <p>23 Q And -- but essential to your theory,</p> <p>24 though, Doctor, at some point, some amount of</p>	<p style="text-align: right;">Page 165</p> <p>1 time; right?</p> <p>2 A Well, the -- again, the -- my opinion</p> <p>3 is not based on how talc migrates or -- or when</p> <p>4 it can migrate. It's simply based on the, again,</p> <p>5 that biological premise, that exposure to talc.</p> <p>6 So I wasn't asked to opine whether or</p> <p>7 not talc exposure in a neighboring tissue could</p> <p>8 cause enough of an inflammatory response to</p> <p>9 affect the ovary.</p> <p>10 So there is the, certainly, the</p> <p>11 uninvestigated secondary effects that perhaps</p> <p>12 talc did not -- is not necessary or -- and</p> <p>13 required to get to the ovary to cause that</p> <p>14 effect. I'm -- I'm just not aware of any studies</p> <p>15 that have made that delineation of talc exposure</p> <p>16 to neighboring or surrounding organs.</p> <p>17 There is limited or some suggestion</p> <p>18 regarding the inflammatory response related to</p> <p>19 talc exposure in the lung that suggests that any</p> <p>20 talc exposure causes an inflammatory response.</p> <p>21 Again, but I can't point you to evidence that</p> <p>22 would take that inflammatory response and tie it</p> <p>23 specifically to ovarian cancer.</p> <p>24 So, again, my answer is there is not</p>

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<p style="text-align: right;">Page 166</p> <p>1 enough evidence to -- to support nor refute that</p> <p>2 any talc exposure can lead to an increased risk</p> <p>3 of ovarian cancer. What I do know from my review</p> <p>4 of the literature is the studies that looked at</p> <p>5 that specific exposure --</p> <p>6 And, to be clear, none of the</p> <p>7 epidemiology studies in humans quantitated the</p> <p>8 amount of talc reaching the ovary. It was simply</p> <p>9 the exposure and the -- and the perineal use of</p> <p>10 talc. So I think any discussion about how much</p> <p>11 did it reach the ovary and how long was it in the</p> <p>12 ovary is all hypothetical.</p> <p>13 Q Why don't we go off the record and take</p> <p>14 a break.</p> <p>15 Thank you, Doctor.</p> <p>16 VIDEOGRAPHER:</p> <p>17 Going off the record. The time is</p> <p>18 11:51 a.m.</p> <p>19 (LUNCH RECESS.)</p> <p>20 VIDEOGRAPHER:</p> <p>21 We're back on the record. The time is</p> <p>22 12:52 p.m.</p> <p>23 MS. BROWN:</p> <p>24 Q Welcome back, Doctor.</p>	<p style="text-align: right;">Page 168</p> <p>1 by well-established biological facts?</p> <p>2 A I would say the -- that chronic</p> <p>3 inflammation as a component of causing ovarian</p> <p>4 cancer is well established by biologically</p> <p>5 plausible facts.</p> <p>6 Q And what are those facts?</p> <p>7 A I think a number of studies that</p> <p>8 include the, first, the -- that talc or talcum</p> <p>9 powder causes inflammation. These exist in a</p> <p>10 number of forms, including very recent -- recent</p> <p>11 research by Dr. Saed, as we were -- touched on a</p> <p>12 little bit earlier in the -- in his paper, as</p> <p>13 well as classical studies with talc pleurodesis</p> <p>14 where there's -- you know, the fundamentals of</p> <p>15 that treatment is the inflammatory response</p> <p>16 caused by talc.</p> <p>17 Q Uh-huh.</p> <p>18 A And, so, that would be the -- some of</p> <p>19 the -- two examples of where factual information</p> <p>20 or at least observations that are supportive</p> <p>21 of -- of that information, you know, being</p> <p>22 considered as a bio- -- part of a biologically</p> <p>23 plausible mechanism.</p> <p>24 Q You would agree, Doctor, that not all</p>
<p style="text-align: right;">Page 167</p> <p>1 You were asked in this case to assess</p> <p>2 whether perineal use of talcum powder products</p> <p>3 induces a biologically plausible mechanism or</p> <p>4 mechanisms that result in ovarian cancer.</p> <p>5 Correct?</p> <p>6 A Correct.</p> <p>7 Q And define for us, if you will,</p> <p>8 "biologically plausible mechanism" as you used it</p> <p>9 in that sentence.</p> <p>10 A Excuse me. A mechanism that is</p> <p>11 biologically plausible, I mean that it is</p> <p>12 supported by either well-established biological</p> <p>13 facts or supported by at least a single line of</p> <p>14 evidence in published literature -- you know,</p> <p>15 generally speaking, peer-reviewed literature but</p> <p>16 certainly not limited to that -- where when you</p> <p>17 take -- when you consider the totality of the</p> <p>18 mechanism, that, essentially, each of the steps</p> <p>19 makes sense and is -- is supported by -- through</p> <p>20 either direct or indirect observations.</p> <p>21 Q Okay. And, in this case, as it relates</p> <p>22 to talcum powder, do you believe that the</p> <p>23 biologically plausible mechanism of chronic</p> <p>24 inflammation causing ovarian cancer is supported</p>	<p style="text-align: right;">Page 169</p> <p>1 inflammation causes cancer; correct?</p> <p>2 A I would say inflammation is not</p> <p>3 singularly responsible for cancer. However, I</p> <p>4 would clarify that the progression from cellular</p> <p>5 transformation to malignant cancer, at least with</p> <p>6 our current understanding of cancer biology,</p> <p>7 appears to have an inflammatory requirement,</p> <p>8 meaning that all cases of chronic inflammation</p> <p>9 don't necessarily cause cancer. However, our</p> <p>10 understanding of malignant transformation appears</p> <p>11 to have, universally, an inflammatory component.</p> <p>12 Q Okay. You would agree, though, that</p> <p>13 not all types of inflammation that the body</p> <p>14 experiences is inflammation that will lead to</p> <p>15 cancer. Correct?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A So I would -- taking a step back</p> <p>19 and -- and -- or to orient us to some of the</p> <p>20 basis of my opinions and some statements on</p> <p>21 general cancer biology --</p> <p>22 MS. BROWN:</p> <p>23 Q Well, let's start with just the</p> <p>24 question, though, Doctor.</p>

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<p>1 A Okay.</p> <p>2 Q Okay. Let's just keep it to an answer</p> <p>3 to the question. And then if you need an</p> <p>4 opportunity to make another statement on the</p> <p>5 record, that's fine.</p> <p>6 MS. O'DELL:</p> <p>7 Excuse me. Just object to the</p> <p>8 direction of the witness.</p> <p>9 Dr. Levy, you can answer a question</p> <p>10 however you'd like.</p> <p>11 MS. BROWN:</p> <p>12 Q And, just to orient you, Doctor, what</p> <p>13 I'm after, the question was: Not all</p> <p>14 inflammation that takes place in the body is</p> <p>15 inflammation that leads to cancer; correct?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A So that, yeah, it's really too general</p> <p>19 a question. So you're -- you're -- what you're</p> <p>20 asking is does all inflammation have the</p> <p>21 potential to have -- have a relationship to</p> <p>22 cancer, and the answer to that is -- is yes, it</p> <p>23 does.</p> <p>24 Now, does every inflammatory response</p>	<p>1 cause cancer. The -- you need a contribution of</p> <p>2 other factors. And what those factors are is --</p> <p>3 some are understood. Some are areas of active</p> <p>4 research.</p> <p>5 In the -- in the specific case of</p> <p>6 ovarian cancer, it does appear, given the</p> <p>7 late- -- given the observations about latency</p> <p>8 period, that some level of chronic inflammation</p> <p>9 appears to be critical, but there is no</p> <p>10 definition of it being required to then having</p> <p>11 acute inflammation, again, in summary, causing</p> <p>12 cellular damage and then chronic inflammation</p> <p>13 providing a -- a supportive environment for that</p> <p>14 transformation.</p> <p>15 And, again, I'm -- I'm generalizing,</p> <p>16 which, as we discussed earlier in the day, cancer</p> <p>17 is very complex, and so we have to be cautious</p> <p>18 with generalizations.</p> <p>19 Q Talc pleurodesis is a medical procedure</p> <p>20 by which talc is injected into the pleura;</p> <p>21 correct?</p> <p>22 A Correct.</p> <p>23 Q And it is done that purposefully to</p> <p>24 elicit an inflammatory response. Correct?</p>
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<p>1 directly cause cancer? And that's a question</p> <p>2 that I would say would be reasonable to -- in</p> <p>3 layperson's terms, in terms of general</p> <p>4 inflammation, is unlikely.</p> <p>5 But there -- their distinction</p> <p>6 between -- is -- you know, stated simply, is</p> <p>7 inflammation is a -- by our current knowledge of</p> <p>8 cancer, is a necessary component of cancer</p> <p>9 progression. That does not equate to all</p> <p>10 inflammation causing cancer.</p> <p>11 MS. BROWN:</p> <p>12 Q Does acute inflammation cause cancer,</p> <p>13 in your mind, Doctor?</p> <p>14 A It is a component of the cancer</p> <p>15 progression process. And, so, in my -- to</p> <p>16 provide a simplistic distinction between them is</p> <p>17 a --</p> <p>18 Acute inflammation which results in</p> <p>19 either an inflammatory response or direct</p> <p>20 cellular insult or injury can be viewed as having</p> <p>21 a -- causing cellular damage that results</p> <p>22 in -- in cellular transformation.</p> <p>23 Now, that is not sufficient for that --</p> <p>24 for those transformed cells to then go on to</p>	<p>1 A That's correct.</p> <p>2 Q And have you looked in consid- --</p> <p>3 forming your opinions in this case at the body of</p> <p>4 epidemiology that has followed folks who received</p> <p>5 talc pleurodesis to see if they developed cancer?</p> <p>6 MS. O'DELL:</p> <p>7 Object.</p> <p>8 A Somewhat, yes.</p> <p>9 MS. BROWN:</p> <p>10 Q And are you familiar with the findings</p> <p>11 of those studies that talc, when injected</p> <p>12 directly into the pleura for the purpose of</p> <p>13 causing inflammation, had not caused cancer?</p> <p>14 MS. O'DELL:</p> <p>15 Object to the form.</p> <p>16 A I would disagree with your conclusions.</p> <p>17 And, in fact, the literature I reviewed has, I</p> <p>18 think, two fundamental concerns. One is the time</p> <p>19 period that these patients were followed post</p> <p>20 pleurodesis, and the other that there -- there</p> <p>21 have been at least one report, perhaps two -- I</p> <p>22 would have to review to make sure I'm speaking</p> <p>23 accurately -- where there was indeed a</p> <p>24 asbestos-like response in the formation of a</p>

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<p style="text-align: right;">Page 174</p> <p>1 mesothelioma-like event in the -- in the -- in 2 the pleural space following talc pleurodesis. 3 However, you know, taking a step back, 4 given the relative rarity of that as a procedure, 5 particularly today, I think drawing conclusions 6 from that as its -- as its relationship to cancer 7 would be difficult, but I -- I do think 8 fundamentally the -- my use of that as an example 9 was not necessarily to tie talc specifically to 10 cancer. It was more to state that it's well 11 established that platy talc individually as it -- 12 used in those procedures causes an inflammatory 13 response. And so, you know -- and that is the 14 primary reason I used or reviewed that literature 15 for that purpose. 16 MS. BROWN: 17 Q Is it your opinion, Doctor, that talc 18 pleurodesis leads to cancer? 19 MS. O'DELL: 20 Object to the form. 21 A It is my opinion that talc pleurodesis 22 creates an environment supportive of cancer. And 23 whether or not some number of individuals may 24 progress, could progress or have progressed to</p>	<p style="text-align: right;">Page 176</p> <p>1 mid-'80s to early '90s. I'd have to, again, have 2 to review that -- 3 I gave that specific example of a 4 patient or cohort of patients that were found to 5 have, again, asbestos-like effects in the lung 6 leading to, at least in a case or more than 7 perhaps more than one case, a mesothelioma-like 8 effect like we -- like I just mentioned. 9 But, again, to point you to the exact 10 reference, I'd have to review. 11 MS. BROWN: 12 Q Are you relying on that reference in 13 forming your opinions in this case? 14 A No. Specifically -- again, to restate 15 the -- my description of the pleurodesis process 16 was to support the early part of the biological 17 mechanism that talc causes inflammation. So 18 that -- and, so, in the lung as a tissue, that 19 progression to cancer is -- is -- I think is a -- 20 is a -- is a supportive observation to the -- to 21 my overall principle. But, again, it's a 22 separate -- separate exposure type, certainly a 23 very different dosing, potentially, and, again, a 24 very different patient, or the patient is a very</p>
<p style="text-align: right;">Page 175</p> <p>1 cancer is -- you know, is -- is of limited 2 knowledge right now. 3 MS. BROWN: 4 Q What scientific support do you have for 5 your opinion that talc pleurodesis creates an 6 environment supportive of cancer? 7 A Oh, just that it causes an inflammatory 8 response. And, as we've been discussing, there 9 is ample evidence surrounding the role of 10 inflammation in cancer. There's a -- you know, 11 in a number of both reference studies and I think 12 generally, I would -- I would state that it's a 13 generally accepted fact in cancer biology. 14 Q What scientific support do you have for 15 your opinion that talc pleurodesis patients later 16 can and do develop cancer? 17 MS. O'DELL: 18 Object to the form. Misstate his 19 testimony. 20 A I'd have to review my -- review some of 21 the literature. And I can take a look if we want 22 to pause for a moment. 23 But there was -- I recall one study 24 involving talc pleurodesis that was maybe</p>	<p style="text-align: right;">Page 177</p> <p>1 different individual in the sense that they 2 obviously have reasons for going through the talc 3 pleurodesis which are -- which are -- which are 4 potentially compounding to the overall phenotype. 5 Q Have you endeavored to quantify the 6 difference between exposure to talc from 7 pleurodesis versus perineal use of cosmetic 8 talcum powder products? 9 MS. O'DELL: 10 Object to the form. 11 A I have -- I have not attempted to 12 delineate those two simply from the perspective 13 that, again, to the biological mechanism, the 14 initial premise is talc causes inflammation. And 15 when I examined literature to look for evidence 16 of that historically, talc pleurodesis is one 17 example of inflammation. There's now others, and 18 there's, subsequent to that, there's been 19 a -- now a number of -- or, you know, probably 20 a -- 21 Dr. Saed is one example of a reasonably 22 comprehensive molecular study examining specific 23 inflammatory markers tied specifically to 24 cellular exposure to, in the case of that paper,</p>

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<p>1 specific products, you know, such as the Shower</p> <p>2 to Shower and the -- and baby powder.</p> <p>3 MS. BROWN:</p> <p>4 Q Do you believe the inflammation caused</p> <p>5 by talc pleurodesis is chronic inflammation that</p> <p>6 leads to cancer?</p> <p>7 MS. O'DELL:</p> <p>8 Objection to form. Asked and answered.</p> <p>9 A Again, I believe the inflammatory</p> <p>10 response to talc exposure, which would include</p> <p>11 talc pleurodesis, induces an inflammatory</p> <p>12 response that would be supportive of cancer</p> <p>13 development and/or progression.</p> <p>14 MS. BROWN:</p> <p>15 Q And what scientific literature other</p> <p>16 than the one study you just referenced for us do</p> <p>17 you rely on for your opinion that talc</p> <p>18 pleurodesis induces an inflammatory response that</p> <p>19 would be supportive of cancer development and/or</p> <p>20 progression?</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form.</p> <p>23 A All my -- my opinion is based on</p> <p>24 connecting two basic concepts. Talc exposure</p>	<p>1 powder products cause chronic inflammation in</p> <p>2 your November 2018 report before having seen the</p> <p>3 Saed paper from 2018; correct?</p> <p>4 MS. O'DELL:</p> <p>5 Object -- object to the form.</p> <p>6 Misstates his testimony.</p> <p>7 A The -- so, as we discussed -- we</p> <p>8 discussed earlier, I had seen abstract</p> <p>9 information as well as earlier publication from</p> <p>10 Dr. Saed's group and that the current 2018 paper,</p> <p>11 while not necessary for the opinions described in</p> <p>12 the report, certainly support those opinions,</p> <p>13 given that it was a direct assessment of specific</p> <p>14 products, specific -- in specific doses applied</p> <p>15 to cellular material and then measurements for</p> <p>16 inflammation made directly on that material.</p> <p>17 So while that particular study was</p> <p>18 not --</p> <p>19 And, again, the -- the earlier studies</p> <p>20 that were used to inform the 2018 paper were</p> <p>21 certainly used in this report and referenced</p> <p>22 the --</p> <p>23 And I'm just recalling when. Or if</p> <p>24 we've refer- -- had the opportunity to reference</p>
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<p>1 causes inflammation. Inflammation has a</p> <p>2 significant role in cancer development.</p> <p>3 And, so, as far as -- each of those is</p> <p>4 supported by individual -- individual studies,</p> <p>5 and -- and now -- as I mentioned, there are now</p> <p>6 studies that directly tie those together in</p> <p>7 observation.</p> <p>8 MS. BROWN:</p> <p>9 Q What is the scientific basis for your</p> <p>10 support that talc exposure causes the type of</p> <p>11 inflammation that has been linked to cancer?</p> <p>12 A The most recent is the Saed publication</p> <p>13 that we discussed and -- or at least has been</p> <p>14 mentioned. In that study, looking at -- there</p> <p>15 was a assessment and, in some cases, a</p> <p>16 quantitation of the specific molecular markers</p> <p>17 for inflammation that were induced, and many</p> <p>18 of -- some of those markers are shared with known</p> <p>19 markers for -- for cancer progression, such as</p> <p>20 CA 125, as well as others.</p> <p>21 Q Are you referring to Saed's 2018 paper,</p> <p>22 Dr. Levy?</p> <p>23 A Yes.</p> <p>24 Q And you formed the opinions that talcum</p>	<p>1 the --</p> <p>2 Yeah. So we reference primarily the</p> <p>3 abstracts and then, again, as well as some of the</p> <p>4 other Saed work, which is the foundation of the</p> <p>5 directed studies that are described in the</p> <p>6 Reproductive Sciences paper that is Exhibit 12.</p> <p>7 MS. BROWN:</p> <p>8 Q Do you know that Dr. Saed is a paid</p> <p>9 expert for the plaintiffs' lawyers in this</p> <p>10 litigation?</p> <p>11 A I am aware. Yes.</p> <p>12 Q Have you considered that fact in</p> <p>13 evaluating Dr. Saed's work?</p> <p>14 A I did.</p> <p>15 Q Other than Dr. Saed's work from 2017</p> <p>16 and 2018, what evidence are you relying on to</p> <p>17 support your opinion that talcum powder produces</p> <p>18 the type of inflammation that can lead to cancer?</p> <p>19 A There has been -- looking through</p> <p>20 the -- there's the Buz'Zard and Lau, 2007. We</p> <p>21 were discussing the Hamilton -- Hamilton paper in</p> <p>22 terms of immune response but then, more</p> <p>23 specifically, the NTP reference in 1993. And in</p> <p>24 those cases, that was either looking at increases</p>

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<p style="text-align: right;">Page 182</p> <p>1 in reactive oxygen species generation --</p> <p>2 THE COURT REPORTER:</p> <p>3 Wait a minute. You have to slow down</p> <p>4 when you read, please.</p> <p>5 MS. O'DELL:</p> <p>6 You may continue.</p> <p>7 A Just to -- before I left off, I think,</p> <p>8 in those mentioned references, the reactive</p> <p>9 oxygen species generation, increased cell</p> <p>10 proliferation, and the use of -- in the specific</p> <p>11 case of Buz'Zard and Lau, was looking at the</p> <p>12 transformation in human ovarian cancer cells that</p> <p>13 were treated with talcum powder -- sorry -- human</p> <p>14 ovarian cells treated with talcum powder.</p> <p>15 MS. BROWN:</p> <p>16 Q Other than Buz'Zard, Hamilton, and NTP,</p> <p>17 is there anything else that you are relying on to</p> <p>18 support your opinion that the inflammation caused</p> <p>19 by talcum powder is the type of inflammation that</p> <p>20 causes cancer?</p> <p>21 A So there's additional references</p> <p>22 mentioned in the report; Gates, Belot, Harper and</p> <p>23 Saed. And then, in addition to that, there was</p> <p>24 a --</p>	<p style="text-align: right;">Page 184</p> <p>1 the details, and I -- there -- I am aware</p> <p>2 of -- mentioned earlier the Woodruff or Woodford,</p> <p>3 the earlier 1971 paper where I couldn't remember</p> <p>4 the author, is one of the earliest studies that I</p> <p>5 came across that had -- it has an animal model</p> <p>6 study.</p> <p>7 MS. BROWN:</p> <p>8 Q Doctor, is it your testimony that --</p> <p>9 First of all, do you think it's -- that</p> <p>10 in opining that there is a biologically plausible</p> <p>11 mechanism by which talcum powder causes chronic</p> <p>12 inflammation that can cause ovarian cancer, is it</p> <p>13 necessary, in your mind, to be able to show in</p> <p>14 animals that talcum powder does just that?</p> <p>15 A That talcum powder causes inflammation?</p> <p>16 Q That causes ovarian cancer.</p> <p>17 A No, I don't -- I don't think that</p> <p>18 that's -- that's certainly not a requirement.</p> <p>19 And the reason I -- the reason I give that answer</p> <p>20 is -- is quite simple; that there is a wide</p> <p>21 diversity of animal model studies that have not</p> <p>22 been able to mimic specifically or correctly</p> <p>23 human cancer for both -- both from a detection</p> <p>24 and most often from a treatment perspective,</p>
<p style="text-align: right;">Page 183</p> <p>1 Make sure I'm referring to the right</p> <p>2 one.</p> <p>3 So those were the -- those were the</p> <p>4 primary references. And then, of course, there</p> <p>5 were supporting materials and other earlier-cited</p> <p>6 work.</p> <p>7 But for the opinion regarding the type</p> <p>8 of inflammation that is caused by exposure to</p> <p>9 talc and as far as its specific relationship to</p> <p>10 cancer, there's -- there's -- I would point to</p> <p>11 the, at least in the Saed work, the specific</p> <p>12 quantitation of a very well-known tumor marker,</p> <p>13 CA 125, also known as mucin-16 elevation in that</p> <p>14 work, and then, in the case of Gates, some of the</p> <p>15 fundamental glutathione S-transferase has been</p> <p>16 associated or has been observed as a higher risk.</p> <p>17 And, so, that would -- those would be</p> <p>18 some examples.</p> <p>19 Q Are you aware of any animal study,</p> <p>20 Dr. Levy, that shows the inflammation caused by</p> <p>21 talcum powder causing precancerous changes?</p> <p>22 MS. O'DELL:</p> <p>23 Object to the form.</p> <p>24 A I would have to review the -- a few of</p>	<p style="text-align: right;">Page 185</p> <p>1 meaning that, fundamentally, humans and most --</p> <p>2 or at least the animal systems used as -- in</p> <p>3 scientific modeling are different. Some of their</p> <p>4 differences are due to different pathways, and</p> <p>5 others of the differences are due to actually,</p> <p>6 you know, fundamental immune system differences.</p> <p>7 Q The Hamilton article that you</p> <p>8 identified for me, we marked earlier in the</p> <p>9 deposition as Exhibit 7. Do you recall that?</p> <p>10 MS. O'DELL:</p> <p>11 Counsel, would you mind just placing</p> <p>12 the exhibits by the witness so he can refer to</p> <p>13 them as he'd like, please.</p> <p>14 A Yes, I recall this.</p> <p>15 MS. BROWN:</p> <p>16 Q And you would agree with me, Doctor,</p> <p>17 that the Hamilton study that we discussed this</p> <p>18 morning concluded that there were no neoplastic</p> <p>19 changes in the animals that were injected with</p> <p>20 talcum powder; correct?</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form. Asked and</p> <p>23 answered.</p> <p>24 A No. No, I -- I wouldn't agree.</p>

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<p style="text-align: right;">Page 186</p> <p>1 MS. BROWN: 2 Q What evidence in Hamilton, Doctor, are 3 you relying on to support your position that 4 Hamilton showed neoplastic changes in animals 5 injected with talc? 6 A Well, I'm not -- I'm not stating that 7 Hamilton specifically showed that. 8 What I'm stating is that -- that there 9 is a Hamilton study as an animal model system to 10 make the conclusion that, in this animal model 11 system, that talc or talcum powder does not -- or 12 that causes or does not cause ovarian cancer is 13 not -- it's -- it is -- it has limitations. 14 And, as we discussed a bit earlier, the 15 two limitations are the very limited time points 16 of the animals. And if we look at the relative 17 and observed time points that we know now, as far 18 as latency period, these are well short of 19 those -- of those periods, even by rat standards, 20 and then the number of treated animals is 21 relatively small at ten. So the... 22 Q Doctor, do you rely on the Hamilton 23 article to support your opinion that talcum 24 powder produces chronic inflammation that causes</p>	<p style="text-align: right;">Page 188</p> <p>1 Q So this article looked at talc that was 2 injected into animals and found no evidence of 3 changes that lead to cancer. Correct? 4 MS. O'DELL: 5 Objection to form. 6 A Over the time period that they -- that 7 the study was performed, they did -- they did 8 not -- they did not report, and, in fact, as you 9 said, their statements are "no evidence of 10 cellular atypia or mitotic activity." 11 MS. BROWN: 12 Q So in opining, as you do in this case, 13 that talcum powder can biologically induce 14 chronic inflammation that causes ovarian cancer, 15 what methodology did you employ to consider the 16 findings of the Hamilton article? 17 A Well, I considered the findings of the 18 Hamilton article, as -- as referenced in the 19 report, primarily showing that talc has an 20 inflammatory or an immune response. And that was 21 the primary inclusion of the -- of the Hamilton 22 paper. 23 Q Not all inflammatory or immune 24 responses lead to cancer; right?</p>
<p style="text-align: right;">Page 187</p> <p>1 ovarian cancer? 2 A No, I don't rely -- again, I don't rely 3 on any -- there's not a reliance on any singular 4 article. 5 Q Did not mean to suggest that, Doctor. 6 I asked you for the scientific support 7 that you have for the opinions you're giving in 8 this litigation, and one of the articles you 9 identified was the Hamilton article. Correct? 10 A Uh-huh. Yes. 11 Q And I -- and this Hamilton article, as 12 we discussed, at page 103, found no evidence of 13 neoplasm in the rats injected with talc. Right? 14 A They -- I -- I don't -- they did 15 not -- I don't recall seeing a description of 16 neoplasm in the Hamilton article. 17 Q Page 103, second column, begins with 18 "No evidence." 19 A "No evidence of cellular atypia." 20 Q Uh-huh. "And concludes that in no 21 ovary was there any evidence of frank neoplasia"; 22 right? 23 A Yes. That's what's written in the 24 paper.</p>	<p style="text-align: right;">Page 189</p> <p>1 MS. O'DELL: 2 Objection. Asked and answered. 3 A As -- as we discussed, not -- not all 4 inflammatory responses have been shown to 5 conclusively lead to cancer. And, so... 6 MS. BROWN: 7 Q And Hamilton does not support the 8 opinion that the type of inflammatory response 9 that talc causes is the type that causes cancer. 10 Fair enough? 11 MS. O'DELL: 12 Object to the form. 13 A No. I would say that's unfair. 14 Because, again, the limitation of the Hamilton 15 study at the time it was performed was -- is a 16 very short timeline. So there is -- it is an 17 incomplete study in the sense that there is 18 certainly the possibility that the first aspect 19 or the first event that we're -- that we've been 20 discussing in cancer biology, the cellular damage 21 to lead to transformation, could have occurred in 22 some of the rat tissues but had not progressed 23 enough or had -- or had taken hold enough to 24 cause or to have that be detected in this</p>

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<p>1 particular study performed in the early '80s.</p> <p>2 And, furthermore, rat -- the rat model</p> <p>3 for human cancer, since this study has been in</p> <p>4 other cases, has some limitations as it relates</p> <p>5 to how applicable it is to the human condition.</p> <p>6 MS. BROWN:</p> <p>7 Q The NTP study that you identified as</p> <p>8 supporting your opinion, Doctor, that also does</p> <p>9 not show evidence of neoplastic changes; is that</p> <p>10 right?</p> <p>11 MS. O'DELL:</p> <p>12 Object to the form.</p> <p>13 Doctor, please feel free to refer to</p> <p>14 the study if you need to.</p> <p>15 A Yeah. I'll do that now.</p> <p>16 (DEPOSITION EXHIBIT NUMBER 15</p> <p>17 WAS MARKED FOR IDENTIFICATION.)</p> <p>18 MS. BROWN:</p> <p>19 Q Doctor, we'll mark as Exhibit 15 to</p> <p>20 your deposition the NTP study to which you were</p> <p>21 referring.</p> <p>22 A Uh-huh.</p> <p>23 Q And this study, as well, does not show</p> <p>24 evidence of neoplastic changes.</p>	<p>1 Q Did you review, Doctor, the --</p> <p>2 And -- and what about the findings of</p> <p>3 NTP support your opinion?</p> <p>4 A Well, first, the inflammatory response,</p> <p>5 given the evidence by the accumulation of</p> <p>6 macrophages, and then, secondly, that in the</p> <p>7 female rats, the incidences of alveolar and</p> <p>8 bronchial or adenoma, carcinoma, and adenoma in</p> <p>9 the 18-milligram-per-meter group were</p> <p>10 significantly greater than those of controls.</p> <p>11 Q So did you consider the FDA's findings</p> <p>12 as it relates to the evaluation of the NTP study?</p> <p>13 MS. O'DELL:</p> <p>14 Object to the form. Vague.</p> <p>15 A Which -- which FDA?</p> <p>16 MS. BROWN:</p> <p>17 Q Have you considered, in connection with</p> <p>18 this case, the FDA's response to the 2014</p> <p>19 citizens petition?</p> <p>20 A Yes. That's familiar. And if I recall</p> <p>21 correctly --</p> <p>22 Or do you have -- is that handy?</p> <p>23 Q We'll mark that as Exhibit 16, Doctor.</p> <p>24 (DEPOSITION EXHIBIT NUMBER 16</p>
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<p>1 MS. O'DELL:</p> <p>2 Object to the form.</p> <p>3 Do you have a copy for me?</p> <p>4 It's what number?</p> <p>5 MS. BROWN:</p> <p>6 Fifteen.</p> <p>7 A I think the -- the important</p> <p>8 distinction in this particular study is this was</p> <p>9 an aerosol-based -- based study. It certainly</p> <p>10 was longer than the Hamilton but was -- was not a</p> <p>11 study that mimics the perineal use of talc.</p> <p>12 MS. BROWN:</p> <p>13 Q And, so, as it relates to your opinion</p> <p>14 in this case, Doctor, that talc induces a chronic</p> <p>15 inflammation that can lead to ovarian cancer, the</p> <p>16 NTP study does not support that, does it?</p> <p>17 MS. O'DELL:</p> <p>18 Object to the form.</p> <p>19 A I would say the study does support my</p> <p>20 opinion regarding talc and its role in</p> <p>21 inflammation. And if we refer to page 6 within</p> <p>22 the first -- the first paragraph, beginning with</p> <p>23 "Accumulations of macrophages."</p> <p>24 MS. BROWN:</p>	<p>1 WAS MARKED FOR IDENTIFICATION.)</p> <p>2 MS. BROWN:</p> <p>3 Q The reason I want to talk to you about</p> <p>4 this is it contains a review of the NTP study we</p> <p>5 were just discussing.</p> <p>6 First of all, did you consider this</p> <p>7 document in connection with your opinions in this</p> <p>8 case?</p> <p>9 A Yes, this document's familiar.</p> <p>10 Q Okay. And do you recall that a cancer</p> <p>11 prevention coalition wrote the FDA requesting</p> <p>12 that a warning label be placed on talcum powder</p> <p>13 products?</p> <p>14 A Yes.</p> <p>15 Q And do you recall, as evidenced on</p> <p>16 page 1, the FDA reviewed the data as it related</p> <p>17 to that question?</p> <p>18 A I -- I recall that the FDA reviewed the</p> <p>19 data and determined that it was insufficient, and</p> <p>20 they did not identify any new compelling</p> <p>21 literature at the time. But this was in 2014.</p> <p>22 Q And the NTP --</p> <p>23 MS. O'DELL:</p> <p>24 Excuse me, counsel.</p>

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<p>1 Were you finished? If you're finished, 2 that's fine. I just didn't know if you completed 3 your -- 4 A I'm just reading. There was one 5 other -- I recall -- 6 MS. BROWN: 7 Q Doctor, the NTP study that you pointed 8 us to was from 1993. Is that right? 9 A I believe that's correct. 10 Q All right. And one of the things that 11 the FDA did in this letter of 2014 is reviewed 12 that study; correct? 13 A Yes. 14 Q And I'll direct you to page 3 of 7. 15 And what the FDA concluded was that the study 16 lacked convincing scientific support because of 17 serious flaws in its design and conduct. 18 Do you see that? 19 MS. O'DELL: 20 Where are you reading? Sorry. 21 MS. BROWN: 22 Page 3. Page 3. 23 MS. O'DELL: 24 Oh. Page 3. Sorry. I thought you</p>	<p>1 the FDA claimed serious flaws. 2 MS. BROWN: 3 Q At the bottom of page 3 -- 4 A I see. 5 Q -- the sentence that begins, "However, 6 this study lacks convincing scientific support 7 because of serious flaws in its design and 8 conduct -- and conduct." 9 Do you see that? 10 A I do. 11 Q And one of the things the FDA points to 12 is that the investigators used micronized talc 13 instead of consumer grade talc, resulting in the 14 experimental protocol not being reflective of 15 human exposure conditions in terms of particle 16 size. 17 Do you see that? 18 A I do. 19 Q Have you made a determination in this 20 case, sir, about the size of the particles in 21 talcum powder products? 22 A I -- I've not made that distinction. 23 And -- 24 Q There's --</p>
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<p>1 said page 2. I'm sorry. 2 MS. BROWN: 3 Q Do you see that, Doctor? 4 A Starting with -- 5 Q Bottom of page 3 -- 6 A -- under toxicology findings? 7 Q So, to orient us here, Doctor, you 8 pointed, as evidence of support of your opinions 9 in this case, to the NTP study. Right? 10 A Correct. 11 Q And the folks who wrote to the FDA 12 requesting a warning on talc, they, too, pointed 13 to that study; right? 14 A Yes. 15 Q All right. And, so, the FDA reviewed 16 that study and, in the letter denying the 17 citizens petition, included its critique of that 18 study; correct? 19 A Correct. 20 Q And one of the things the FDA concluded 21 was that the study had serious flaws. True? 22 MS. O'DELL: 23 Objection to form. 24 A I don't -- do you -- I don't see where</p>	<p>1 A And, furthermore, I think the -- 2 importantly, the -- the flaws that the FDA points 3 out are, you know, not in disagreement with 4 our -- with our discussions surrounding both the 5 inflammatory response and then some of the 6 results there. I don't -- I don't see as a 7 concern -- 8 In fact, the -- it appears the FDA does 9 not disagree with the observation of the evidence 10 of carcinogenic activity in the non-asbestiform 11 talc. I think they -- 12 I share -- 13 Q Let's focus back on the question, 14 Doctor. 15 MS. O'DELL: 16 Excuse me. Let him finish his answer. 17 He's not finished. 18 A So, the, you know, the serious flaws 19 were the, I think, in this case, the specific 20 inclusion of nonasbestos talc and use of 21 micronized talc instead of consumer grade. So I 22 think in that -- in that sense, it's not 23 surprising that it had a different -- perhaps a 24 different response than may be observed with</p>

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<p>1 consumer products or talc that have -- may have</p> <p>2 contaminants, whether it be asbestos or other.</p> <p>3 MS. BROWN:</p> <p>4 Q Do you remember the question I asked,</p> <p>5 Doctor?</p> <p>6 A Perhaps it would be helpful to restate.</p> <p>7 Q I think, probably.</p> <p>8 I asked if you had made a determination</p> <p>9 in this case about the size of the particles in</p> <p>10 talcum powder products.</p> <p>11 A I -- so as far -- a determination, no.</p> <p>12 I would -- I would say I have had an opportunity</p> <p>13 to, you know, review or become more educated in</p> <p>14 the diversity of talc products and the</p> <p>15 interesting geographic relationship to different</p> <p>16 size particles and -- in the presence or absence</p> <p>17 of asbestiform particles in talc, which was a,</p> <p>18 you know, fascinating area to become educated in.</p> <p>19 As far as examining that in each of the</p> <p>20 individual studies, I certainly was able to pay</p> <p>21 attention to earlier or later studies as it</p> <p>22 applied to when there was a specific description</p> <p>23 of the talc, such as in the NTP study where</p> <p>24 there -- that was one of the few that had a</p>	<p>1 when -- when used in the perineum compared to</p> <p>2 inhalation.</p> <p>3 But I have not seen a study that tried</p> <p>4 to distinguish that in terms of having an exposed</p> <p>5 group who inhaled talc only and then looked for</p> <p>6 evidence of the presence in the ovary.</p> <p>7 Q Back to the FDA document we were</p> <p>8 discussing, Doctor, the FDA's critique of the NTP</p> <p>9 study continues on page 4, where the FDA</p> <p>10 identifies that the investigators conceded they</p> <p>11 have problems with the aerosol generation system</p> <p>12 and that the study did not include positive and</p> <p>13 negative dust controls.</p> <p>14 Did you consider those critiques in</p> <p>15 evaluating the NTP study in this case?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A Well, I -- I certainly considered --</p> <p>19 you know, considered them in -- as -- as I would</p> <p>20 consider any -- any other evidence or opinion</p> <p>21 on -- on these relevant subjects.</p> <p>22 MS. BROWN:</p> <p>23 Q The FDA went on to conclude, Doctor,</p> <p>24 that, in light of the shortcoming, a panel of</p>
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<p>1 specific determination.</p> <p>2 But I was basing my opinions on the</p> <p>3 general behavior, summarized behavior of talc</p> <p>4 based on the available evidence.</p> <p>5 Q In forming your opinions in this case,</p> <p>6 Doctor, have you concluded that a particular</p> <p>7 route of exposure is more likely when women are</p> <p>8 using talcum powder products perineally?</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form.</p> <p>11 A Certainly it would seem logical that</p> <p>12 the route of talc exposure would be related to</p> <p>13 the area that the talc is used.</p> <p>14 MS. BROWN:</p> <p>15 Q As such, do you believe and have you</p> <p>16 assumed for purposes in your -- of your opinions</p> <p>17 in this case that talc more likely migrates from</p> <p>18 the perineum to the ovaries, as opposed to talc</p> <p>19 being inhaled and then traveling down to the</p> <p>20 ovaries?</p> <p>21 A The evidence I've seen would suggest</p> <p>22 that that migration that you described from the</p> <p>23 perineum through the vagina into the fallopian</p> <p>24 tubes into the ovary is certainly far more likely</p>	<p>1 experts at the 1994 ISRTP/FDA workshop declared</p> <p>2 that the 1993 NTP study has no relevance to human</p> <p>3 risk.</p> <p>4 Do you share that conclusion?</p> <p>5 MS. O'DELL:</p> <p>6 Object to the form.</p> <p>7 A I do not. And I think, importantly,</p> <p>8 you know, even there at the bottom of page 4,</p> <p>9 their point number 4 saying a cogent biological</p> <p>10 mechanism by which talc might lead to ovarian</p> <p>11 cancer is lacking.</p> <p>12 MS. BROWN:</p> <p>13 Q Uh-huh.</p> <p>14 A I believe, as we're discussing today,</p> <p>15 subsequent research and subsequent studies</p> <p>16 have -- and including my report, have helped</p> <p>17 define that plausible biological mechanism</p> <p>18 which -- by which talc may lead to ovarian</p> <p>19 cancer.</p> <p>20 Q In answering my question, Doctor, you</p> <p>21 pointed to a different portion of the same page</p> <p>22 we were discussing; correct?</p> <p>23 A Correct.</p> <p>24 Q And what you pointed to was the FDA's</p>

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<p style="text-align: right;">Page 202</p> <p>1 conclusion here in 2014 that a cogent biological</p> <p>2 mechanism by which talc might lead to ovarian</p> <p>3 cancer is lacking. Correct?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form.</p> <p>6 A I -- I would disagree in the general</p> <p>7 nature of your statement and clarify it by saying</p> <p>8 the FDA found a lack of that mechanism based on</p> <p>9 the submitted literature of the citizen petition.</p> <p>10 MS. BROWN:</p> <p>11 Q So do you understand, Doctor, in</p> <p>12 evaluating the FDA's response, that they, in</p> <p>13 fact, did their own investigation in addition to</p> <p>14 the literature that was provided to them at the</p> <p>15 time?</p> <p>16 MS. O'DELL:</p> <p>17 Objection. Misstates the record.</p> <p>18 A Well, my reading of it, it says</p> <p>19 they -- that their -- that the scientific</p> <p>20 literature considered was submitted in support of</p> <p>21 both citizen petitions. And...</p> <p>22 MS. BROWN:</p> <p>23 Q Are you finished, Doctor?</p> <p>24 A Yes. I was just looking to see if</p>	<p style="text-align: right;">Page 204</p> <p>1 A I -- I disagree with the -- or I -- I</p> <p>2 have found, based on a review of the literature,</p> <p>3 that there are now additional supporting studies</p> <p>4 that would -- that would refute some of these</p> <p>5 conclusions of -- by the FDA review.</p> <p>6 Q And explain to us, then, Doctor, what</p> <p>7 methodology you employed or what research you</p> <p>8 conducted to reach a conclusion different from</p> <p>9 the FDA's conclusion in 2014.</p> <p>10 A I think, similar to what the FDA</p> <p>11 described, my review is of the literature now,</p> <p>12 you know, through 2018, examining the available</p> <p>13 information regarding inflammatory response to</p> <p>14 talc and then talc exposure as it relates</p> <p>15 to -- to the initiation of progression of cancer.</p> <p>16 Q Dr. Leavy -- Dr. Levy, do you think</p> <p>17 that the FDA, in concluding, as they did in 2014,</p> <p>18 that a cogent biological mechanism by which talc</p> <p>19 might lead to ovarian cancer is lacking, do you</p> <p>20 think they were wrong at that time?</p> <p>21 A I would -- I -- I would say that they</p> <p>22 were incomplete at that time. And, in fact, you</p> <p>23 know, one of the --</p> <p>24 If we -- if we look at page 5 in the</p>
<p style="text-align: right;">Page 203</p> <p>1 there was a notation about further --</p> <p>2 Q I'll direct you, Doctor, to page 4, the</p> <p>3 second full paragraph that begins "In addition,</p> <p>4 the FDA stated."</p> <p>5 "In addition, we reviewed relevant</p> <p>6 toxicity literature (consisting of 15 articles</p> <p>7 from 1980 to 2008) not cited in your petition to</p> <p>8 determine if there was additional support at this</p> <p>9 point in time for your suggested warning label."</p> <p>10 Do you see that?</p> <p>11 A I do.</p> <p>12 Q And, based on the FDA's review of all</p> <p>13 the literature that they investigated at the</p> <p>14 time, they concluded that a cogent biological</p> <p>15 mechanism by which talc might lead to ovarian</p> <p>16 cancer was lacking. Right?</p> <p>17 MS. O'DELL:</p> <p>18 Objection to form.</p> <p>19 MS. BROWN:</p> <p>20 Q That was their conclusion; correct?</p> <p>21 A Yes, as written, that was their -- that</p> <p>22 was the FDA's conclusion.</p> <p>23 Q And you, Dr. Levy, disagree with that</p> <p>24 conclusion; correct?</p>	<p style="text-align: right;">Page 205</p> <p>1 one, two -- third full paragraph beginning with</p> <p>2 "while there exists," where the FDA does agree</p> <p>3 about the -- that it's plausible that perineal</p> <p>4 talc and other particulates reach the endometrial</p> <p>5 cavity and -- and associated organs and may</p> <p>6 elicit a foreign-body-type reaction and</p> <p>7 inflammatory response that in some exposed women</p> <p>8 may progress to epithelial cancers. What they do</p> <p>9 state, "However, there has been no conclusive</p> <p>10 evidence to support causality."</p> <p>11 So I would suggest that this paragraph</p> <p>12 is in support of the biologically plausible</p> <p>13 mechanism that I included in the report and</p> <p>14 that -- and, as we've been discussing, I</p> <p>15 haven't -- we -- we've not been discussing a</p> <p>16 causal or a formal causal evaluation.</p> <p>17 Q What information did you rely on,</p> <p>18 Doctor, in reaching the conclusion that there is</p> <p>19 a biological mechanism that the FDA did not?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form. Misstates his</p> <p>22 testimony.</p> <p>23 A I'm stating that the -- as we</p> <p>24 discussed, as we've been discussing today, the --</p>

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<p>1 the response to talc -- the response to talc</p> <p>2 exposure as an inflammatory response is supported</p> <p>3 by a number of studies, including the NTP study,</p> <p>4 which, although the FDA had some concerns with,</p> <p>5 the FDA also made statements regarding the</p> <p>6 exposure to talc and other particulates having an</p> <p>7 inflammatory response and that some exposed</p> <p>8 women's may have progressed to epithelial</p> <p>9 cancers.</p> <p>10 So, again, they're -- I think</p> <p>11 they -- they're in agreement there. So even the</p> <p>12 concerns with the study withstanding, there's --</p> <p>13 there's -- there's -- I still -- I still think</p> <p>14 the FDA report is in support of the mechanism</p> <p>15 that we've been discussing.</p> <p>16 MS. BROWN:</p> <p>17 Q The FDA concludes that a cogent</p> <p>18 biological mechanism by which talc might lead to</p> <p>19 ovarian cancer is lacking, do they not?</p> <p>20 MS. O'DELL:</p> <p>21 Objection to form. Asked and answered.</p> <p>22 A But I would al- -- I would say the FDA</p> <p>23 contr- -- perhaps contradicts itself later in the</p> <p>24 same document, stating that there is both an</p>	<p>1 studies on which you're relying?</p> <p>2 A Not -- not for the contents of the</p> <p>3 report. Not that I'm aware of. I think we've --</p> <p>4 we've already discussed some of the other</p> <p>5 references contained in the report</p> <p>6 below and -- or at least by mention and Gates.</p> <p>7 (DEPOSITION EXHIBIT NUMBER 17</p> <p>8 WAS MARKED FOR IDENTIFICATION.)</p> <p>9 MS. BROWN:</p> <p>10 Q I'm gonna mark as Exhibit 17 to your</p> <p>11 deposition the Buz'Zard study that you mentioned</p> <p>12 a moment ago. Do you recall that?</p> <p>13 A Yes.</p> <p>14 Q Do you rely on the Buz'Zard study in</p> <p>15 supporting your view that chronic inflammation</p> <p>16 from talcum powder use can cause ovarian cancer?</p> <p>17 MS. O'DELL:</p> <p>18 17?</p> <p>19 MS. BROWN:</p> <p>20 Yes.</p> <p>21 A Sorry. Can you restate your question?</p> <p>22 It wasn't...</p> <p>23 MS. BROWN:</p> <p>24 Q Do you rely on what we've marked as</p>
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<p>1 inflammatory response and that in some exposed</p> <p>2 women they may progress to epithelial cancer.</p> <p>3 MS. BROWN:</p> <p>4 Q Other than the Woodruff article,</p> <p>5 Doctor, are you aware of any other study in</p> <p>6 animals that shows inflammation leading to</p> <p>7 cancer?</p> <p>8 MS. O'DELL:</p> <p>9 Objection to form. Other than those</p> <p>10 he's mentioned?</p> <p>11 A Yeah. I -- I would have to -- that</p> <p>12 would -- that would require review of the</p> <p>13 literature to -- to speak generally to animal</p> <p>14 studies and inflammation leading to cancer.</p> <p>15 MS. BROWN:</p> <p>16 Q Let me rephrase.</p> <p>17 In terms of your opinion here that talc</p> <p>18 causes chronic inflammation that causes ovarian</p> <p>19 cancer, you identified the Hamilton study, the</p> <p>20 NTP study, and the Woodruff study as animal</p> <p>21 studies that support that view. True?</p> <p>22 A I identified those studies as</p> <p>23 supportive of my -- of my opinion, yes.</p> <p>24 Q Are you aware of any additional animal</p>	<p>1 Exhibit 17, the Buz'Zard study, to support your</p> <p>2 view that talcum powder causes chronic</p> <p>3 inflammation that leads to ovarian cancer?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form.</p> <p>6 A As we've discussed, not singularly, but</p> <p>7 the -- as part -- as part of a complete picture</p> <p>8 of talc causing reactive oxygen species</p> <p>9 generation and other inflammatory responses,</p> <p>10 certainly this is a study that supports that</p> <p>11 opinion.</p> <p>12 MS. BROWN:</p> <p>13 Q Did you consider the type of cells that</p> <p>14 were evaluated in the Buz'Zard study?</p> <p>15 MS. O'DELL:</p> <p>16 Objection to form. Vague.</p> <p>17 A Certainly in terms of the overall</p> <p>18 experimental design.</p> <p>19 MS. BROWN:</p> <p>20 Q Did those -- were those normal human</p> <p>21 ovarian cells?</p> <p>22 A The -- the author has labeled them as</p> <p>23 normal human ovarian cells. But the -- you know,</p> <p>24 one of the key characteristics and similar to our</p>

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<p>1 comments on -- on animal systems is all -- all</p> <p>2 in vitro or in vivo studies that are using cell</p> <p>3 lines or animals have limitations. And in this</p> <p>4 case, you know, cell lines are particularly</p> <p>5 notorious in research in general for</p> <p>6 their -- for -- having to use care in extending</p> <p>7 findings to, you know, broad mechanisms in a --</p> <p>8 in a complex organism or in the human body.</p> <p>9 Q Sure.</p> <p>10 What you're -- what you're saying is</p> <p>11 you've got to be careful taking the findings from</p> <p>12 one cell study and extrapolating that to humans.</p> <p>13 Fair?</p> <p>14 MS. O'DELL:</p> <p>15 Object to the form.</p> <p>16 A The -- I think you have to be careful</p> <p>17 in evaluating each study in using the relevant</p> <p>18 components of that study and observations in that</p> <p>19 study as part of an overall mechanism and whether</p> <p>20 it's supportive or refutes such a mechanism.</p> <p>21 So --</p> <p>22 MS. BROWN:</p> <p>23 Q Did -- did you exercise that care here</p> <p>24 as it relates to the Buz'Zard study?</p>	<p>1 MS. O'DELL:</p> <p>2 Figure 3.</p> <p>3 A Figure 3?</p> <p>4 The one interesting observation in</p> <p>5 these two figures, both Figure 3A and Figure 3B,</p> <p>6 being the percentage of reactive oxygen specie</p> <p>7 generation in two different cell types, one in --</p> <p>8 one in Panel A and one in Panel B, is -- what I</p> <p>9 did not see included, if I --</p> <p>10 And I'm reading to see if I recall</p> <p>11 correctly.</p> <p>12 -- was a -- the -- the cell viability</p> <p>13 assay that they use for normalization has</p> <p>14 a -- somewhat of a limitation in that it -- it</p> <p>15 doesn't measure cell senescence. It only</p> <p>16 measures cell death. And, so, they -- not to</p> <p>17 dis- -- not that I disagree with your observation</p> <p>18 that it did not show the sig- -- significant</p> <p>19 increase, but there is the possibility that the</p> <p>20 reason that you see an actual decrease in the RS</p> <p>21 generation at the higher doses of talc is that</p> <p>22 cells have gone senescent and are essentially no</p> <p>23 longer responding to that increased dose.</p> <p>24 So I think there's at least two</p>
Page 211	Page 213
<p>1 A So the Buz'Zard study, you know,</p> <p>2 primarily, as -- as referenced, was to illustrate</p> <p>3 a study that showed an increase in reactive</p> <p>4 oxygen species generation, and that's the -- the</p> <p>5 primary purpose, or I should say primary</p> <p>6 observation on the -- from this.</p> <p>7 Now, certainly, the study contained</p> <p>8 more observations than that and certainly had</p> <p>9 some -- you know, a number of other components.</p> <p>10 Q How does the Buz'Zard study support</p> <p>11 your view that talcum powder causes chronic</p> <p>12 inflammation that causes ovarian cancer?</p> <p>13 A So the Buz'Zard study supports the view</p> <p>14 that exposure to talcum powder causes an</p> <p>15 inflammatory response.</p> <p>16 Q And that inflammatory response you saw</p> <p>17 in the Buz'Zard study does not increase with</p> <p>18 increasing doses of talcum powder. Correct?</p> <p>19 A I have to review. I believe that -- I</p> <p>20 believe their figures suggest --</p> <p>21 You know, are you referring</p> <p>22 specifically to their reaction -- reactive oxygen</p> <p>23 specie generation?</p> <p>24 Q Correct.</p>	<p>1 different ways to interpret some of these</p> <p>2 results. But I don't disagree with your</p> <p>3 observations regarding Figure 3.</p> <p>4 MS. BROWN:</p> <p>5 Q This study was conducted in a</p> <p>6 nutritional lab, not a cancer lab. True?</p> <p>7 A I'm -- I'm not aware of the type of</p> <p>8 laboratory or even the...</p> <p>9 Q And the study was -- the purpose of the</p> <p>10 study was to assess whether there was a certain</p> <p>11 effect of pine bark supplement? Is that right?</p> <p>12 MS. O'DELL:</p> <p>13 Objection to form.</p> <p>14 A They were looking at the -- the effect</p> <p>15 of a proprietary -- as stated by the authors, a</p> <p>16 proprietary mixture of water soluble</p> <p>17 bioflavonoids extracted from French maritime pine</p> <p>18 bark.</p> <p>19 MS. BROWN:</p> <p>20 Q Uh-huh.</p> <p>21 And did you investigate whether the</p> <p>22 ovarian cells that they used here were</p> <p>23 genetically altered?</p> <p>24 A No, I did not investigate that.</p>

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<p>1 Q Did you --</p> <p>2 I'm sorry. Were you done?</p> <p>3 A No. I would say it's fair -- it's fair</p> <p>4 to say that, you know, that the -- whether</p> <p>5 they're genetically altered or not, the -- the --</p> <p>6 you know, the same potential limitations as far</p> <p>7 as extrapolation to the human system would apply</p> <p>8 for any signs.</p> <p>9 But, again, the purpose of the Buz'Zard</p> <p>10 study, as -- as referenced in the report, was to</p> <p>11 indicate that there are studies that have shown</p> <p>12 an increase in reactive oxygen specie generation</p> <p>13 under exposure to -- to talc. And I think the</p> <p>14 study is reasonably clear on that increase</p> <p>15 relative to control.</p> <p>16 Q Except what this study showed, Doctor,</p> <p>17 is the more talc you give, the decrease from</p> <p>18 baseline in the reactive oxygen species.</p> <p>19 Correct?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form. Asked and</p> <p>22 answered. Misstates the testimony.</p> <p>23 MS. BROWN:</p> <p>24 Q Take a look at Figure 3; right, Doctor?</p>	<p>1 Q My question was, Doctor, what this</p> <p>2 study shows is the more talc you give, the less</p> <p>3 ROS generation there is. True?</p> <p>4 MS. O'DELL:</p> <p>5 Objection to form.</p> <p>6 A Again, under -- under the conditions of</p> <p>7 this particular study.</p> <p>8 MS. BROWN:</p> <p>9 Q Do you think the Buz'Zard study is</p> <p>10 scientifically reliable?</p> <p>11 A I have no basis to -- to suggest that</p> <p>12 it's -- that it's not reliable.</p> <p>13 Q Do you think that --</p> <p>14 A But I think there -- it does -- if</p> <p>15 there is a -- as we discussed earlier, an</p> <p>16 importance to not overgeneralize conclusions or</p> <p>17 lack of conclusions as, you know, outside of the</p> <p>18 system under study.</p> <p>19 Q If -- I want you to assume that the</p> <p>20 Buz'Zard study used genetically altered ovarian</p> <p>21 cells that did not have the p53 protein. Would</p> <p>22 that affect your analysis of Buz'Zard?</p> <p>23 MS. O'DELL:</p> <p>24 Object to the form.</p>
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<p>1 A No. I agree. But, as stated, and an</p> <p>2 important clarification is whether that decrease</p> <p>3 is significant relative to the biology is -- is</p> <p>4 unknown.</p> <p>5 Q Right.</p> <p>6 This study certainly does not</p> <p>7 conclusively show that the more talc you give,</p> <p>8 the more ROS is generated. Correct?</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form.</p> <p>11 A In these particular cell lines under</p> <p>12 these conditions, the -- the study certainly did</p> <p>13 not draw that conclusion.</p> <p>14 MS. BROWN:</p> <p>15 Q In fact, what this study shows is the</p> <p>16 more talc you give, the less of -- of ROS</p> <p>17 generation you have. Doesn't it?</p> <p>18 MS. O'DELL:</p> <p>19 Object to the form.</p> <p>20 A I think importantly in this study, the</p> <p>21 time dependency for each of the doses is more</p> <p>22 important at the doses rather than comparing dose</p> <p>23 to dose.</p> <p>24 MS. BROWN:</p>	<p>1 A Well, that's -- that's an impossible</p> <p>2 question. Like you can't have --</p> <p>3 Well, you can't call a cell type a</p> <p>4 normal ovarian cell and -- absent p53 protein.</p> <p>5 You're -- it'd be -- you're fundamentally</p> <p>6 changing the biology of the cell as it relates to</p> <p>7 ovarian cancer or cancer in general.</p> <p>8 MS. BROWN:</p> <p>9 Q Because p53 is something that you have</p> <p>10 in your genes that prevents against ovarian</p> <p>11 cancer. True?</p> <p>12 MS. O'DELL:</p> <p>13 Objection.</p> <p>14 A So p5- -- p53 is a well-known, often</p> <p>15 mutated gene in a number of human cancers.</p> <p>16 MS. BROWN:</p> <p>17 Q And, so, if the ovarian cells that were</p> <p>18 studied in Buz'Zard did not have p53, it will</p> <p>19 call into question the study. Fair?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form.</p> <p>22 A It would be difficult to answer. From</p> <p>23 the perspective of the presence or absence</p> <p>24 of -- of p53 having an effect on the ability of a</p>

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<p style="text-align: right;">Page 218</p> <p>1 cell to generate reactive oxygen species under --</p> <p>2 under exposure to a substance like talcum powder</p> <p>3 would need to be tested directly.</p> <p>4 MS. BROWN:</p> <p>5 Q Fair to say, in your mind, a cell</p> <p>6 missing p53 is not a normal human ovarian cell.</p> <p>7 True?</p> <p>8 A That is true.</p> <p>9 (DEPOSITION EXHIBIT NUMBER 18</p> <p>10 WAS MARKED FOR IDENTIFICATION.)</p> <p>11 MS. BROWN:</p> <p>12 Q Handing you what we've marked as</p> <p>13 Exhibit 18 to your deposition, it's a review</p> <p>14 article titled "Perineal Talc Use and Ovarian</p> <p>15 Cancer," by Ross Penninkilampi.</p> <p>16 Do you see that?</p> <p>17 A I do.</p> <p>18 Q This is an article that you cited in</p> <p>19 your report; correct?</p> <p>20 A Correct.</p> <p>21 Q Does this article support your view</p> <p>22 that there is a biolo -- in part --</p> <p>23 Strike that.</p> <p>24 Does this article, in part, support</p>	<p style="text-align: right;">Page 220</p> <p>1 available literature and, in this case, review a</p> <p>2 meta-analysis of some reasonably large-scale</p> <p>3 studies to try to bring the proposed biologically</p> <p>4 plausible mechanism and include the -- the</p> <p>5 available epidemiological information for those,</p> <p>6 such as the Penninkilampi and Eslick paper we're</p> <p>7 discussing.</p> <p>8 Q What methodology did you employ in</p> <p>9 terms of reviewing the Penninkilampi findings as</p> <p>10 it relates to the question you addressed in your</p> <p>11 report?</p> <p>12 MS. O'DELL:</p> <p>13 Object to the form.</p> <p>14 A I -- I used the same methodology for</p> <p>15 the other studies as a review of the paper and</p> <p>16 its -- and its methods and conclusions.</p> <p>17 MS. BROWN:</p> <p>18 Q Do you believe this review, systematic</p> <p>19 review and meta-analysis, provides evidence that</p> <p>20 there's a biologically plausible mechanism by</p> <p>21 which talc can cause ovarian cancer?</p> <p>22 A Yes. It provided -- it shows an</p> <p>23 association between talc use and ovarian cancer.</p> <p>24 I don't -- I don't believe this particular study</p>
<p style="text-align: right;">Page 219</p> <p>1 your opinion in this case that there is a</p> <p>2 biologically plausible mechanism by which talcum</p> <p>3 powder can cause ovarian cancer which can</p> <p>4 cause --</p> <p>5 Strike that. Gonna do it again.</p> <p>6 Does this article support your view, in</p> <p>7 part, that talcum powder can cause chronic</p> <p>8 inflammation that can cause ovarian cancer?</p> <p>9 A This is an article I considered in</p> <p>10 the -- in the overall review and, in the</p> <p>11 conclusions of this article, found a -- an</p> <p>12 association between perineal talc use and ovarian</p> <p>13 cancer, according to the authors.</p> <p>14 So it was supportive of the proposed</p> <p>15 mechanism but was, again, in part.</p> <p>16 Q And, on page 13 and 14 of your report,</p> <p>17 you, in fact, reference the Penninkilampi study</p> <p>18 and some of its conclusions; correct?</p> <p>19 A Correct. On the -- on the bottom of</p> <p>20 page 13, yes.</p> <p>21 Q And what was the purpose of including</p> <p>22 this description of Penninkilampi in your expert</p> <p>23 report, Doctor?</p> <p>24 A Just to be sure to be -- to include</p>	<p style="text-align: right;">Page 221</p> <p>1 goes on to specifically elucidate causation, but</p> <p>2 it certainly shows the association.</p> <p>3 Q Well, the study specifically says that</p> <p>4 causation cannot be found, based on the results.</p> <p>5 Right?</p> <p>6 MS. O'DELL:</p> <p>7 Objection to form.</p> <p>8 MS. BROWN:</p> <p>9 Q If you look at page 42, Doctor, the</p> <p>10 very end of that first paragraph, "A certain</p> <p>11 causal link between talc use and ovarian cancer</p> <p>12 has not been established."</p> <p>13 Do you see that?</p> <p>14 MS. O'DELL:</p> <p>15 Where are you? Page 42. Where are you</p> <p>16 reading, please?</p> <p>17 MS. BROWN:</p> <p>18 Page 42, the end of the first</p> <p>19 paragraph.</p> <p>20 A Yes, I see that.</p> <p>21 MS. BROWN:</p> <p>22 Q Do you agree with that statement,</p> <p>23 Doctor, that a causal link between talc use and</p> <p>24 ovarian cancer has not yet been established?</p>

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<p>1 MS. O'DELL: 2 Objection. 3 A No, I wouldn't. But, again, my review 4 of this was to tie the biologically plausible 5 mechanism to, you know, human observation, not 6 provide a evaluation of the -- of the causal 7 link. 8 And I think the -- I would suspect that 9 the -- 10 I'm also not aware of a study that has 11 been able to -- or a -- or a -- what would be 12 necessary -- 13 I'm not aware of a study that has been 14 able to provide all of the recognized and 15 established methodology for causation and have 16 that applied in -- in talc. 17 MS. BROWN: 18 Q You're not aware of any study in the 19 talc epidemiology that has concluded that talcum 20 powder causes ovarian cancer; correct? 21 MS. O'DELL: 22 Objection to form. 23 A I'm aware of a number of studies that 24 have shown a strong correlation between the two.</p>	<p>1 examine that comprehensively, when you consider 2 the etiology of a disease and the latency periods 3 that have been observed in ovarian cancer in 4 general and the meta review by both this earlier 5 paper by Penninkilampi and then their subsequent 6 later work, you have a challenge of a -- in a 7 cohort study, a disease that is somewhat rare, 8 coupled with a exposure and latency period that's 9 been, in the -- in the limited number of studies 10 that have looked at this, appears to be quite 11 long, and then when you couple in the -- the 12 ethical concerns of actually performing a trial, 13 where it becomes a very difficult causation bar 14 to reach. 15 And, so, instead, we rely on the 16 case -- the available case-control data and then 17 systematic and meta-analysis reviews such as some 18 of the epidemiologists have performed to make 19 assessments into the likelihood that -- and the 20 strength of the association between talc use and 21 ovarian cancer. 22 Q Are you intending to provide an opinion 23 on the strength of the association between talc 24 use and ovarian cancer as evidenced in the</p>
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<p>1 But I would have to defer to the epidemiology 2 expert witnesses as to their opinion on 3 causation. 4 MS. BROWN: 5 Q One of the things you told us that you 6 reviewed in connection with your opinion was the 7 talc epidemiology. Is that right? 8 A That's right. 9 Q Did you conduct a review of all of the 10 available epidemiology on talcum powder use and 11 ovarian cancer? 12 A I certainly tried to review it as 13 comprehensively as -- as possible. 14 Q And, in connection with that review, 15 you'll agree there is not a single study that 16 concludes there is a causal association between 17 talcum powder use and ovarian cancer; correct? 18 MS. O'DELL: 19 Objection to form. 20 A So I would -- I would -- interestingly, 21 there -- it's -- it becomes a -- as more -- as 22 more and more information has become available 23 over the last few years, that becomes a more and 24 more difficult bar to meet, simply because, to</p>	<p>1 epidemiology? 2 MS. O'DELL: 3 Object to the form. 4 A No. My -- my opinions are limited to 5 the biologically plausible mechanism and then 6 examining whether that biologically plausible 7 mechanism presented is supported by observations 8 in -- in available human studies. 9 MS. BROWN: 10 Q And when you say your opinion is 11 limited to a biological plausible mechanism, are 12 you talking of the theoretical concept or are you 13 talking about in the context of women using 14 talcum powder perineally? 15 A In the context -- 16 MS. O'DELL: 17 Object to the form. 18 THE WITNESS: 19 Sorry. 20 MS. O'DELL: 21 Excuse me. 22 A In the -- in the context of women using 23 talcum powder perineally specifically, and 24 then -- and then certainly also the -- some of</p>

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<p>1 the fundamental aspects of that mechanism may</p> <p>2 apply to other exposures as well.</p> <p>3 MS. BROWN:</p> <p>4 Q Like what?</p> <p>5 A Well, the -- the other exposure we've</p> <p>6 been discussing, in -- in that some of the</p> <p>7 studies looked at inhalation exposure, et cetera.</p> <p>8 But the primary review and the primary</p> <p>9 opinion is based on the perineal use of talcum</p> <p>10 powder and that exposure that, as -- as we</p> <p>11 discussed earlier, has a -- certainly a strong</p> <p>12 association with perineal use and an exposure --</p> <p>13 exposure in the ovaries.</p> <p>14 Q Your opinion is that if a woman uses</p> <p>15 talcum powder perineally, there is a biologically</p> <p>16 plausible mechanism by which enough talcum powder</p> <p>17 can migrate from outside of her vagina to her</p> <p>18 ovary to cause chronic inflammation that can lead</p> <p>19 to ovarian cancer?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form.</p> <p>22 A So I'd say that the first part of your</p> <p>23 question is well established and included in the</p> <p>24 statements from FDA and others that that</p>	<p>1 trial that would examine that in a well-powered</p> <p>2 fashion to answer that question directly. And,</p> <p>3 certainly, as of today, there would be some</p> <p>4 significant ethical concerns with that design.</p> <p>5 So, instead, we rely on the cohort and</p> <p>6 case-control studies that are available. And</p> <p>7 those, again, studies are supporting an</p> <p>8 association between talc use and ovarian cancer.</p> <p>9 MS. BROWN:</p> <p>10 Q Right. But I'm talking about for your</p> <p>11 opinion that it's biologically plausible for</p> <p>12 perineal use of talc to cause ovarian cancer,</p> <p>13 have you made a determination, in your mind, of</p> <p>14 how long that perineal use has to take place for?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form.</p> <p>17 A I wasn't asked to provide -- to provide</p> <p>18 that opinion on -- and it -- on that length or</p> <p>19 exposure or duration.</p> <p>20 Again, it was -- the focus was on the</p> <p>21 biologically plausible mechanism that if you have</p> <p>22 a single exposure and that -- that that single</p> <p>23 exposure through to any other may be sufficient</p> <p>24 to trigger that mechanism.</p>
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<p>1 migration does occur.</p> <p>2 And then the next step in the -- in the</p> <p>3 mechanism is that that causes inflammation which,</p> <p>4 again, as we've discussed, in a number of</p> <p>5 studies, that the inflammation occurs and then,</p> <p>6 in these human studies, in their systematic</p> <p>7 review, that there is a clear association or a --</p> <p>8 a observed association between perineal use of</p> <p>9 talc and the detection of ovarian cancer at some</p> <p>10 point in the -- in the women's lives and, in the</p> <p>11 case of the Penninkilampi, with a relationship to</p> <p>12 the number of lifetime applications.</p> <p>13 So considering those things together,</p> <p>14 yes, there is a biologically plausible mechanism</p> <p>15 for perineal talc use through to ovarian cancer.</p> <p>16 MS. BROWN:</p> <p>17 Q Have you -- is -- is your opinion that</p> <p>18 there's a biologically plausible mechanism</p> <p>19 dependent on a particular number of years of</p> <p>20 perineal use?</p> <p>21 MS. O'DELL:</p> <p>22 Objection to form.</p> <p>23 A The -- so the -- as we just discussed,</p> <p>24 there's no -- I can't point to a formal clinical</p>	<p>1 MS. BROWN:</p> <p>2 Q That's helpful, Doctor.</p> <p>3 So, as I understand your opinion, your</p> <p>4 piece of the puzzle here was to look at whether</p> <p>5 one single application of talcum powder to the</p> <p>6 perineum could lead to chronic inflammation that</p> <p>7 could cause ovarian cancer.</p> <p>8 MS. O'DELL:</p> <p>9 Objection.</p> <p>10 MS. BROWN:</p> <p>11 Q Correct?</p> <p>12 A No, no.</p> <p>13 MS. O'DELL:</p> <p>14 Object to the form of the question.</p> <p>15 A No. That's not my -- my statement.</p> <p>16 My statement was that, based on the</p> <p>17 evidence available, that there's a biologically</p> <p>18 plausible mechanism for the -- for the cellular</p> <p>19 changes that -- that is independent of the</p> <p>20 exposure.</p> <p>21 MS. BROWN:</p> <p>22 Q You've made a determin--</p> <p>23 A But certainly a single exposure would</p> <p>24 be the physically minimum number. And I</p>

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<p style="text-align: right;">Page 230</p> <p>1 believe -- I think we --</p> <p>2 Q That's what I want to understand. And</p> <p>3 how you -- how you make this biological</p> <p>4 plausibility determination is to evaluate a</p> <p>5 single exposure? Is that right?</p> <p>6 MS. O'DELL:</p> <p>7 Object to the form.</p> <p>8 A No.</p> <p>9 MS. O'DELL:</p> <p>10 Misstates his testimony.</p> <p>11 A That's -- that's not what I'm stating.</p> <p>12 My -- my statement is that the -- the</p> <p>13 biologically plausible mechanism is a mechanism</p> <p>14 that is independent of the exposure and that, as</p> <p>15 part of the description of that mechanism and the</p> <p>16 evaluation of the studies supporting that</p> <p>17 mechanism through an inflammatory response, the</p> <p>18 question of exposure, number, and duration,</p> <p>19 length of time, et cetera, would be a separate</p> <p>20 evaluation.</p> <p>21 MS. BROWN:</p> <p>22 Q Is your opinion that talcum powder</p> <p>23 products cause chronic inflammation that cause</p> <p>24 ovarian cancer limited to perineal use, or have</p>	<p style="text-align: right;">Page 232</p> <p>1 effect, it doesn't matter at all how much of the</p> <p>2 product is used?</p> <p>3 MS. O'DELL:</p> <p>4 Objection.</p> <p>5 MS. BROWN:</p> <p>6 Q Do you see what I'm struggling with?</p> <p>7 Can you help me understand? If I'm trying to</p> <p>8 figure out does X cause Y, it sounds like what</p> <p>9 you're saying is it doesn't matter how much X you</p> <p>10 have.</p> <p>11 MS. O'DELL:</p> <p>12 Objection to form.</p> <p>13 A So we're -- we're talking about</p> <p>14 mech- -- so mechanistic action --</p> <p>15 MS. BROWN:</p> <p>16 Q Okay.</p> <p>17 A -- which means the -- you set aside the</p> <p>18 "how much." And the question is, from -- on a</p> <p>19 molecular level, can the presence of a particular</p> <p>20 compound in a particular location cause a</p> <p>21 biological effect. And, so, that is the primary</p> <p>22 focus of the opinion in the -- in the paper or --</p> <p>23 sorry -- in my report.</p> <p>24 And then extending that to how much,</p>
<p style="text-align: right;">Page 231</p> <p>1 you also evaluated body use of talcum powder</p> <p>2 products?</p> <p>3 MS. O'DELL:</p> <p>4 Object to the form.</p> <p>5 A My -- my focus was on the perineal use,</p> <p>6 and that's where the majority of the studies</p> <p>7 have -- have examined. So the focus was on</p> <p>8 perineal use of talcum powder.</p> <p>9 MS. BROWN:</p> <p>10 Q And in conducting that evaluation, the</p> <p>11 results of which are contained in your report,</p> <p>12 you did not endeavor to quantify how much talcum</p> <p>13 powder used perineally could possibly migrate to</p> <p>14 the ovaries; is that right?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form. Asked and answered</p> <p>17 maybe ten times already today.</p> <p>18 But you may answer the question.</p> <p>19 A Yeah. I -- I wasn't asked to -- to</p> <p>20 provide that opinion or attempt that</p> <p>21 quantitation.</p> <p>22 MS. BROWN:</p> <p>23 Q So when you conduct your analysis of</p> <p>24 whether something can biologically cause an</p>	<p style="text-align: right;">Page 233</p> <p>1 how long, and the dur- -- and then the intensity</p> <p>2 or duration of the biological effect, again, is a</p> <p>3 separate -- would be a separate discussion or</p> <p>4 separate study.</p> <p>5 So, again, to clarify, the focus had</p> <p>6 been on that -- some of the fundamental</p> <p>7 mechanisms, talc -- a talcum powder exposure to</p> <p>8 an inflammatory response to the inflammatory</p> <p>9 response causing cancer.</p> <p>10 Again, the -- I would refer to and</p> <p>11 defer to the other experts in epidemiology</p> <p>12 regarding their opinions on the validity of</p> <p>13 the asso- -- validity and strength of the</p> <p>14 associations, again, from a formal epidemiology</p> <p>15 perspective.</p> <p>16 My review of those studies has ind- --</p> <p>17 has relied on their conclusions, and, then, in my</p> <p>18 own review of their -- of their methodology</p> <p>19 showing a increasing association, that is the</p> <p>20 bookends of my -- of the mechanism I proposed.</p> <p>21 So what this study is looking at is</p> <p>22 perineal use of talc, getting cancer.</p> <p>23 The -- what I've proposed is in the</p> <p>24 middle. But this, again, the epidemiology</p>

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<p style="text-align: right;">Page 234</p> <p>1 studies are asking how many times, what, and 2 where, but there's been no evaluation that I'm 3 aware of that looks at exactly how the talc was 4 applied, when and where. Instead, it was asked 5 number of lifetime applications, duration of use, 6 and examining latency period. 7 And when I examine that information 8 from the perspective of that biological 9 mechanism, I, you know, notice some parallels in 10 between latency period averaging roughly twenty 11 years, which -- which mimics somewhat what's 12 observed in the asbestos field as far as, you 13 know, lung effect latency. 14 And then that continues into the 15 constituent -- or the other constituent 16 components of some of the products, including 17 testing into asbestos and some of the -- and 18 heavy metal exposure, et cetera, that those are, 19 again, supportive and offer a potential 20 amplifying effect in that -- in that mechanism, 21 given the nature of those other components. 22 Q What's the scientific support for the 23 amplification effect you just described? 24 A Just that the presence of</p>	<p style="text-align: right;">Page 236</p> <p>1 that opinion from the observations of a couple of 2 different studies, including the recent Saed 3 paper that did look at the specific consumer 4 product every -- you know, showing a -- if we do 5 it by way of comparison, between the Buz'Zard 6 paper and the recent Saed, seemingly a larger 7 magnitude of reactive oxygen species generation. 8 But, again, that is a -- extrapolating against 9 two different studies. 10 Q Do you -- 11 MS. O'DELL: 12 Excuse me. We've been going about an 13 hour and 20 minutes, maybe a little more. 14 MS. BROWN: 15 I think a little less. But I'm gonna 16 finish up. Then we'll take a quick break. 17 Q Does that work for you, Doctor? 18 I just want to finish Penninkilampi if 19 we can. 20 MS. O'DELL: 21 How much more do you have to go? 22 MS. BROWN: 23 About five or ten minutes. 24 MS. O'DELL:</p>
<p style="text-align: right;">Page 235</p> <p>1 more -- the -- 2 So if we extend beyond the opinion that 3 talc, as a com- -- as a singular compound, causes 4 inflammation and then also, based on the reviewed 5 expert reports, find that testing of talc has 6 been shown to contain asbestos or asbestos 7 fibers, that the presence of now two potential 8 insulting -- 9 I'm making a hypothesis or making a 10 statement that the -- you can have -- the more 11 biologically active compounds you have in an 12 exposure such as talc plus asbestos plus chromium 13 and then plus a milieu of chemicals that are in 14 fragrances may have an amplification effect on 15 that exposure and as part of that overall 16 biological mechanism. 17 Q Are you relying on a particular article 18 or any published scientific support for the 19 amplification argument? 20 MS. O'DELL: 21 Object to the form. He's answered the 22 question. 23 A No. I -- I don't know of a study that 24 is delineated. The -- it would be synthesizing</p>	<p style="text-align: right;">Page 237</p> <p>1 If you need a break, we can break now. 2 Or we can keep -- if you would like to wait five 3 or ten minutes, that's fine. Whatever's best for 4 you, Doctor. 5 THE WITNESS: 6 Yeah, if we could break now, that would 7 be great. 8 VIDEOGRAPHER: 9 Going off the record. The time is 10 2:10 p.m. 11 (OFF THE RECORD.) 12 VIDEOGRAPHER: 13 We're back on the record. The time is 14 2:26 p.m. 15 MS. BROWN: 16 Q Welcome back, Doctor. 17 Before we took a break, we were 18 discussing the Penninkilampi article. Do you 19 remember that? 20 A I do. 21 Q And one of the things the authors of 22 this very recent meta-analysis discussed is the 23 potential mechanism of ovarian cancer. Correct? 24 And I'll direct your attention to the</p>

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<p style="text-align: right;">Page 238</p> <p>1 discussion that begins on page 45. In the second</p> <p>2 sentence, the authors conclude here that the</p> <p>3 mechanism by which perineal talc use may increase</p> <p>4 the risk of ovarian cancer is uncertain.</p> <p>5 Do you see that?</p> <p>6 A I see that sentence, yes.</p> <p>7 Q And they go on to discuss the theory</p> <p>8 that talc could produce a chronic inflammatory</p> <p>9 response which could predispose to the</p> <p>10 development of ovarian cancer.</p> <p>11 Do you see that?</p> <p>12 A Yes.</p> <p>13 Q Okay. And they go on to explain a</p> <p>14 little bit more about the theory. Do you see</p> <p>15 that?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A Specifically the sentence beginning</p> <p>19 with "it is argued"?</p> <p>20 MS. BROWN:</p> <p>21 Q Uh-huh. "It is argued that cellular</p> <p>22 injury, oxidative stress, and local increase in</p> <p>23 inflammatory mediators such as cytokines,</p> <p>24 prostaglandins may be mutagenic and, hence,</p>	<p style="text-align: right;">Page 240</p> <p>1 presence of the talc or a continued chronic</p> <p>2 immune response or chronic inflammatory response,</p> <p>3 again, either directly or indirectly related to</p> <p>4 the exposure, would help support a environment</p> <p>5 that would allow the cancer progression to occur.</p> <p>6 So that is simply delineating those --</p> <p>7 those two things as it relates to inflammation</p> <p>8 and talc exposure.</p> <p>9 Q So you described two potential</p> <p>10 responses to talc right now. Correct?</p> <p>11 MS. O'DELL:</p> <p>12 Objection to form.</p> <p>13 A At least two, yes.</p> <p>14 MS. BROWN:</p> <p>15 Q Okay. And one is an acute inflammatory</p> <p>16 response; correct?</p> <p>17 A Yes.</p> <p>18 Q And for that you point to the Saed data</p> <p>19 on reactive oxygen species; is that right?</p> <p>20 MS. O'DELL:</p> <p>21 Objection to form.</p> <p>22 A That is one example, yes.</p> <p>23 MS. BROWN:</p> <p>24 Q Okay. Are there -- is there other</p>
<p style="text-align: right;">Page 239</p> <p>1 promote carcinogenesis."</p> <p>2 Do you see that?</p> <p>3 A I see that.</p> <p>4 Q This sentence refers to chronic</p> <p>5 inflammation promoting cancer. Correct?</p> <p>6 MS. O'DELL:</p> <p>7 Object to the form.</p> <p>8 A No. This -- this refers to that the</p> <p>9 presence of -- proposed that talc as a</p> <p>10 foreign -- that the presence of a foreign body</p> <p>11 would instigate a chronic inflammatory response.</p> <p>12 That's the statement in the paper.</p> <p>13 MS. BROWN:</p> <p>14 Q Is it your opinion that talcum powder</p> <p>15 can cause chronic inflammation that initiates</p> <p>16 cancer?</p> <p>17 A It's -- so it is -- it is my opinion</p> <p>18 is, part of the mechanism, that talcum powder can</p> <p>19 have two effects related to inflammation. The</p> <p>20 first effect is an acute effect resulting in</p> <p>21 cellular damage, and that is supported by the</p> <p>22 study showing increase in reactive oxygen species</p> <p>23 related to talc.</p> <p>24 The -- beyond that, the continued</p>	<p style="text-align: right;">Page 241</p> <p>1 scientific support for your opinion that talc can</p> <p>2 cause acute inflammation?</p> <p>3 A So it's any of the similar studies to</p> <p>4 Saed. And I would have to double-check the</p> <p>5 references, but they would have -- you know, any</p> <p>6 of the --</p> <p>7 MS. O'DELL:</p> <p>8 Feel free to --</p> <p>9 MS. BROWN:</p> <p>10 Q Buz'Zard?</p> <p>11 A So Buz'Zard would be one. Harper and</p> <p>12 Saed is -- is another.</p> <p>13 Q In your --</p> <p>14 A And so -- yeah. Yes, Buz'Zard and Lau</p> <p>15 and then -- yeah. So that would --</p> <p>16 Q Okay. So for your opinion that talc</p> <p>17 causes an acute inflamm- -- inflammatory</p> <p>18 response, you rely on the cell studies done by</p> <p>19 Saed and Buz'Zard; correct?</p> <p>20 MS. O'DELL:</p> <p>21 Objection to the form.</p> <p>22 A Yes, among others.</p> <p>23 MS. BROWN:</p> <p>24 Q In your opinion, Doctor, does that</p>

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<p style="text-align: right;">Page 242</p> <p>1 acute inflammatory response resolve?</p> <p>2 A I don't -- I don't have any evidence to</p> <p>3 suggest it resolves or not. The --</p> <p>4 Again, getting back to the mechanism</p> <p>5 that has been -- that I've described and is</p> <p>6 supported by the literature we've been discussing</p> <p>7 is that there is a acute response as well as</p> <p>8 evidence for talc causing a more chronic</p> <p>9 inflammatory response. And so I've proposed a</p> <p>10 mechanism by which both of those can contribute</p> <p>11 to or enhance the development of cancer.</p> <p>12 Q Can both of those inflammatory</p> <p>13 responses that you just described initiate</p> <p>14 cancer?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form. Asked and</p> <p>17 answered.</p> <p>18 A They are certainly a component of that.</p> <p>19 And so, again, to restate the</p> <p>20 mechanism, the acute inflammatory response or</p> <p>21 the -- the formation of reactive oxygen species</p> <p>22 has been known for decades to cause cellular</p> <p>23 damage, and then cellular damage can result in</p> <p>24 mutation of -- of DNA.</p>	<p style="text-align: right;">Page 244</p> <p>1 they're not -- I don't have evidence to -- to</p> <p>2 delineate those specifically, other than -- other</p> <p>3 than the supported mechanism that an acute</p> <p>4 response can cause cellular damage, and then a</p> <p>5 chronic response can cause cellular damage and be</p> <p>6 supportive of that continued -- that continued</p> <p>7 transformation.</p> <p>8 So they are -- they -- those -- those</p> <p>9 two delineated immune responses can either work</p> <p>10 in -- in concert with each other, but there is no</p> <p>11 evidence to suggest that one is insufficient</p> <p>12 relative to the other in terms of progression of</p> <p>13 the disease.</p> <p>14 And I think specific to the -- to the</p> <p>15 supported mechanism is that there -- I'm not</p> <p>16 making that distinction in the -- in the report.</p> <p>17 MS. BROWN:</p> <p>18 Q Right. In your report, you don't talk</p> <p>19 about acute versus chronic inflammation.</p> <p>20 Correct?</p> <p>21 A That's correct. I don't delineate the</p> <p>22 two. Right.</p> <p>23 Q But, here today, as we discuss in more</p> <p>24 detail your opinions, you're explaining that</p>
<p style="text-align: right;">Page 243</p> <p>1 And then when you also consider the</p> <p>2 full constituents of the products, the potential</p> <p>3 presence --</p> <p>4 And this gets back to our earlier</p> <p>5 discussions about amplification.</p> <p>6 Components such as chromium, which have</p> <p>7 a direct DNA-damaging effect, can also</p> <p>8 ampli- -- again, add to the level of cellular</p> <p>9 damage present.</p> <p>10 And then the continued inflammatory</p> <p>11 response, whether it is a -- related to the</p> <p>12 initial acute response and a continuation of that</p> <p>13 or is a separate chronic inflammatory response</p> <p>14 would then support the environment necessary for</p> <p>15 the malignant transformation or the malignancy of</p> <p>16 the cancer to become what we -- what we would</p> <p>17 generally refer to as ovarian cancer.</p> <p>18 Q In your opinion, the chronic</p> <p>19 inflammation promotes the cancer but does not</p> <p>20 initiate it?</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form. Asked and</p> <p>23 answered.</p> <p>24 A No. So I wouldn't -- I would say</p>	<p style="text-align: right;">Page 245</p> <p>1 you're -- in your mind, you see two potential</p> <p>2 inflammatory responses from talc. Right?</p> <p>3 MS. O'DELL:</p> <p>4 Object to the form.</p> <p>5 A I would disagree. I would say that</p> <p>6 I -- I -- based on the information and studies,</p> <p>7 the -- the review of other expert reports, that</p> <p>8 it presents a supported opinion that talc has an</p> <p>9 ability to cause an acute response as well as a</p> <p>10 chronic response.</p> <p>11 And, so, then, today we are discussing</p> <p>12 using that data in support of the -- of the</p> <p>13 mechanism as to how those -- those two responses</p> <p>14 can work together or separately in the</p> <p>15 progression of ovarian cancer.</p> <p>16 MS. BROWN:</p> <p>17 Q At the time you wrote your report in</p> <p>18 November of 2018, were you of the view that talc</p> <p>19 can cause both acute and chronic inflammatory</p> <p>20 response?</p> <p>21 A Yes. I mean, it was -- I was of the</p> <p>22 view it causes an inflammatory response. And</p> <p>23 then, as I continued to review information</p> <p>24 available, it became clear that the talc</p>

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<p style="text-align: right;">Page 246</p> <p>1 response, being an inflammatory response in 2 totality, may have the ability to have 3 those -- to -- to have two independent responses 4 in tissues. 5 Q And, in your opinion, can both the 6 acute inflammatory response and the chronic 7 inflammatory response separately cause ovarian 8 cancer? 9 A Under the -- the mechanism I've 10 proposed, yes, that would be a -- a possibility 11 that they could separately cause, given that 12 they -- they're both inflammatory responses, they 13 both cause cellular damage. 14 And in the case -- in this case, 15 delineating the acute from chronic was more to 16 clarify the cellular damage aspect, the 17 transformative aspect of cancer from the -- the 18 necessary tumor progression aspects of cancer to 19 actually progress to disease. 20 Q In your opinion, Doctor, does talc 21 always first cause an acute reaction and then a 22 chronic reaction? 23 MS. O'DELL: 24 Object to the form.</p>	<p style="text-align: right;">Page 248</p> <p>1 important. 2 Q So there is a length of time or an 3 amount of exposure that would cause a chronic 4 inflammation that is different from the length of 5 time and the magnitude of exposure that will 6 cause an acute inflammation? 7 MS. O'DELL: 8 Object to the form. Misstates his 9 testimony. 10 A Yeah, no. Not -- that's not what 11 I -- that's not what I've stated. 12 I've simply stated that if we -- if we 13 look at the -- what is known about inflammation 14 and the biological response to foreign bodies, 15 you can have an initial acute response mediated 16 by the immune system and mediated by some of the 17 cellular damage that takes place, and then that 18 same response may continue in a chronic form for 19 some period of time and at some level of 20 magnitude. 21 Now, certainly there is likely a 22 dependency or, I should say, likely a 23 relationship to the amount of exposure and the 24 magnitude of that response.</p>
<p style="text-align: right;">Page 247</p> <p>1 A I -- I -- I don't have evidence 2 to -- to state that and would defer to some of 3 the other expert witnesses, like Dr. Saed, for 4 opinions on acute response versus chronic. 5 MS. BROWN: 6 Q In your opinion, though, you have at 7 least delineated in your mind two different types 8 of inflammatory responses. Correct? 9 MS. O'DELL: 10 Objection to form. 11 A I've -- I have described two mechanisms 12 for inflammation that -- that both can -- are 13 both supportive of the overall mechanism that 14 we're discussing. 15 MS. BROWN: 16 Q And is it -- is there a length of time 17 that differentiates an acute inflammatory 18 response from a chronic inflammatory response? 19 A Certainly I would say there -- in my 20 opinion, there would -- it would be a potential 21 time dependency or a magnitude dependency to 22 delineate an acute versus chronic response. But, 23 again, for the purpose of the biological 24 mechanism, separating them on those lines is not</p>	<p style="text-align: right;">Page 249</p> <p>1 But, again, the -- the opinions here 2 are specific to the mechanism and the initial 3 elucidation of that response and, you know, 4 not -- not on a quantitation of a -- a 5 dose-response relation -- or a dose-response 6 curve or relationship. 7 MS. BROWN: 8 Q Do you believe that every time a talc 9 particle enters the human body, it produces a 10 inflammatory response? 11 A All of the evidence would suggest yes. 12 Q Have you considered Heller's 1996 study 13 on that score? 14 A I would have to -- 15 On the score of inflammatory response? 16 Q Do you recall that Heller looked at 17 benign ovarian tissue and identified the 18 potential presence of talc? 19 A Sounds familiar. 20 Q I'll hand it to you. 21 (DEPOSITION EXHIBIT NUMBER 19 22 WAS MARKED FOR IDENTIFICATION.) 23 MS. BROWN: 24 Q Handing you, Doctor, what we've marked</p>

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<p>1 Heller's '96 article as Exhibit 19.</p> <p>2 And what I want to ask you about is</p> <p>3 Heller's finding as it relates to no reaction to</p> <p>4 the talc particle. Did you consider that --</p> <p>5 MS. O'DELL:</p> <p>6 Object to the form.</p> <p>7 MS. BROWN:</p> <p>8 Q -- in forming your opinion here?</p> <p>9 MS. O'DELL:</p> <p>10 Excuse me. Object to the form.</p> <p>11 MS. BROWN:</p> <p>12 Q I'll direct you, Doctor.</p> <p>13 On page 1508 of the Heller article,</p> <p>14 right above the comments section, "The</p> <p>15 investigators on this study concluded no evidence</p> <p>16 or response to talc, such as foreign body giant</p> <p>17 cell reactions or fibrosis in the tissue."</p> <p>18 My question is whether, in your</p> <p>19 opinion, every time talc is -- enters the body,</p> <p>20 it necessarily produces an inflammatory response.</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form.</p> <p>23 A No. My opinion is that every time talc</p> <p>24 enters the body, that has the potential to cause</p>	<p>1 mechanism that talc causes inflammation and then</p> <p>2 inflammation has a role in ovarian cancer.</p> <p>3 Extending that to circumstances where</p> <p>4 an exposure would not cause inflammation is -- is</p> <p>5 not germane to that -- to that mechanism and, in</p> <p>6 fact, again, not supported by literature to show</p> <p>7 that, you know, that a single exposure or some</p> <p>8 number of exposures are necessary or sufficient</p> <p>9 for a particular phenotype.</p> <p>10 MS. BROWN:</p> <p>11 Q So this Heller study purports to have</p> <p>12 found talc in ovarian tissue without an</p> <p>13 inflammatory response; right?</p> <p>14 MS. O'DELL:</p> <p>15 Object to the form.</p> <p>16 A In looking at their --</p> <p>17 Just one moment.</p> <p>18 So this was a --</p> <p>19 So is your -- is your question that</p> <p>20 the -- if the -- if the author showed talc being</p> <p>21 present in normal ovarian tissue?</p> <p>22 Q Well, first my question is did you</p> <p>23 consider this article in connection with your</p> <p>24 opinions in the case?</p>
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<p>1 an immune response.</p> <p>2 MS. BROWN:</p> <p>3 Q Have you made a determination about</p> <p>4 whether or not that always happens?</p> <p>5 A I'll have --</p> <p>6 MS. O'DELL:</p> <p>7 Object to the form. It's vague.</p> <p>8 A I'm not aware of any --</p> <p>9 There -- there -- these -- none of the</p> <p>10 studies that have been reviewed have been</p> <p>11 designed to answer the question of "if ever."</p> <p>12 MS. BROWN:</p> <p>13 Q So, in your view, then, it's an open</p> <p>14 question about whether talc can be inside the</p> <p>15 body and not produce an inflammatory response.</p> <p>16 MS. O'DELL:</p> <p>17 Object.</p> <p>18 MS. BROWN:</p> <p>19 Q Is that fair?</p> <p>20 MS. O'DELL:</p> <p>21 Excuse me. Objection to form.</p> <p>22 Misstates his testimony.</p> <p>23 A So my -- my -- my testimony regarding</p> <p>24 the mechanism is that there is a well-supported</p>	<p>1 A I don't recall this article</p> <p>2 specifically, and I don't believe I cited it.</p> <p>3 I guess there's -- no.</p> <p>4 Q And then my second question, Doctor, is</p> <p>5 is it your opinion that every time the human body</p> <p>6 is exposed to particles of talc, it necessarily</p> <p>7 produces an inflammatory response that can either</p> <p>8 promote or initiate cancer of the ovaries?</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form.</p> <p>11 A No. My --</p> <p>12 MS. O'DELL:</p> <p>13 Vague.</p> <p>14 A My comment was that the -- that any</p> <p>15 exposure to talc, particularly the perineal</p> <p>16 exposure to talc, has the potential to cause an</p> <p>17 inflammatory reaction.</p> <p>18 I don't have any evidence that all of</p> <p>19 the studies that we've been reviewing are in</p> <p>20 support -- are in support of that mechanism, but</p> <p>21 I don't know of a study that perhaps has been</p> <p>22 able to draw a conclusion, from a similar size</p> <p>23 study, to show that you can get significant talc</p> <p>24 accumulation without an inflammatory response.</p>

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<p>1 MS. BROWN: 2 Q Do you think you need significant talc 3 accumulation in the human body to cause or 4 promote ovarian cancer? 5 MS. O'DELL: 6 Objection to form. 7 A I wasn't asked to -- to provide -- 8 provide that opinion. 9 And, again, referring to the studies 10 that have -- that were reviewed and included in 11 the report, there is a relationship between 12 lifetime exposure and an increased risk in the 13 epidemiology reports. 14 But more detail on that in this 15 discussion, I would defer to the epidemiology 16 experts. But the -- there -- there does appear 17 to be a -- more of a response based on more talc 18 in the -- in the studies referenced. 19 MS. BROWN: 20 Q So on -- 21 Do you have any reason to dispute the 22 findings of Heller here of talc in the ovaries 23 without a foreign body reaction? 24 MS. O'DELL:</p>	<p>1 A In -- in terms of cancer, the 2 epidemiology would suggest -- or I would say 3 the -- the evidence in the literature is -- does 4 not allow that question to be answered, and the 5 reason being is when you look at the latency of 6 the disease and the progression of the disease 7 and the challenges in detecting it, there just 8 has not been enough time with the, perhaps, rigor 9 of analysis that is undergoing now to make that 10 assessment of is it 100 percent of the time or is 11 it something less than 100 percent of the time. 12 I think, statistically speaking, 13 there -- the only data that -- that is available 14 for review is -- is what is contained in some of 15 the meta-analysis and epidemiology studies 16 showing a significant increased risk to ovarian 17 cancer based on exposure to talc. And it 18 would -- it would only be -- I think it would be 19 inappropriate at this time to try to infer what 20 percentage of time that would be indicative of 21 for exposure. 22 Q Have the plaintiffs' lawyers shared 23 with you expert reports from their expert 24 pathologists who have looked at ovarian tissue of</p>
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<p>1 Objection. 2 A I guess my -- I have some -- I guess I 3 have some concerns with some of the methodology 4 as it relates to the detection of the... 5 MS. BROWN: 6 Q Do you think it's possible, Doctor, for 7 talc to enter the body and -- and be completely 8 inert and not cause any reaction? 9 MS. O'DELL: 10 Object to the form. 11 A So my -- the -- the mechanism I've 12 proposed is -- is based -- you know, based on the 13 literature, is that talc causes an inflammatory 14 response and that inflammatory response is 15 supportive of progression to ovarian cancer. 16 MS. BROWN: 17 Q Does that happen 100 percent of the 18 time? 19 MS. O'DELL: 20 Object to the form. In terms of 21 inflammatory response or in terms of cancer? 22 MS. BROWN: 23 Q If you don't understand the question, 24 you'll let me know.</p>	<p>1 plaintiffs in this litigation, purported to find 2 talc with no foreign body reaction? 3 MS. O'DELL: 4 Objection. There have been no 5 case-specific pathology reports disclosed in the 6 litigation we're here about today. And if 7 there's something else you're talking about, you 8 should be specific. 9 A The -- I don't recall a pathology 10 report. I've seen expert reports from 11 epidemiologists, OB-GYN and -- and some -- and 12 other scientists. But I don't recall a specific 13 pathology report. 14 MS. BROWN: 15 Q If the biologically plausible mechanism 16 that you posit in your report is true, would you 17 expect that the pathology slides of women with 18 ovarian cancer who have used talc would evidence 19 talcum powder with a foreign body reaction? 20 MS. O'DELL: 21 Object to the form. Incomplete 22 hypothetical. 23 A That, I would have to ask how you're 24 defining a foreign body reaction.</p>

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<p style="text-align: right;">Page 258</p> <p>1 MS. BROWN:</p> <p>2 Q Well, would you expect to see some</p> <p>3 evidence of inflammation in the ovarian tissue of</p> <p>4 women who used talcum powder products?</p> <p>5 MS. O'DELL:</p> <p>6 Object to the form. Incomplete</p> <p>7 hypothetical.</p> <p>8 A Overall, speaking to, as we were</p> <p>9 discussing earlier, the potential for that</p> <p>10 inflammatory response remains. But given the</p> <p>11 heterogeneity in individuals, their overall</p> <p>12 health, their natural variation in the levels of</p> <p>13 activities of antioxidants, et cetera, I -- I</p> <p>14 would state that I would expect a variety of</p> <p>15 magnitude of response to a foreign body like talc</p> <p>16 among the individuals exposed to it.</p> <p>17 MS. BROWN:</p> <p>18 Q You'd expect to see something; right?</p> <p>19 MS. O'DELL:</p> <p>20 Object to the form.</p> <p>21 A No, not necessarily, because it -- it</p> <p>22 very much depends on the timing that's -- that is</p> <p>23 observed, how -- what methodology is used to</p> <p>24 detect the presence of talc or detect the</p>	<p style="text-align: right;">Page 260</p> <p>1 mentioned some of the other subtypes and the</p> <p>2 common gene mutations that go along with them and</p> <p>3 as, again, supportive of the same mechanism. And</p> <p>4 I think, if anything, the -- the current data</p> <p>5 would suggest a -- a higher prevalence of a</p> <p>6 particular subtype of cancer but certainly not</p> <p>7 the -- the mechanism doesn't -- is not exclusive</p> <p>8 to any one type.</p> <p>9 Q In your view, all types of epithelial</p> <p>10 ovarian cancer can be caused by inflammation?</p> <p>11 A No. That's -- that's not my statement.</p> <p>12 I would say all types of ovarian cancer are</p> <p>13 supported by an inflammatory response but that,</p> <p>14 as from a causative perspective, that's not what</p> <p>15 the mechanism is provided as an opinion as to</p> <p>16 cause. It's more that the -- an inflammatory</p> <p>17 response plays a role in disease initiation</p> <p>18 and/or progression.</p> <p>19 Q In your view, Dr. Levy, it is</p> <p>20 biologically plausible for inflammation to cause</p> <p>21 all types of epithelial ovarian cancer; true?</p> <p>22 A Again, I'm not -- I've not been</p> <p>23 speaking to inflammation as a causative -- as a</p> <p>24 cause of ovarian cancer. It is a factor in --</p>
<p style="text-align: right;">Page 259</p> <p>1 presence of the inflammatory response, if it's,</p> <p>2 you know, done histopathologically, if it is</p> <p>3 based on a reactive oxygen species assay.</p> <p>4 So given the -- speaking in general</p> <p>5 terms, I think it's just inappropriate to make a</p> <p>6 conclusion as to that, yes, you would always</p> <p>7 expect to see something.</p> <p>8 I would -- again, to restate what was</p> <p>9 stated earlier, any -- any exposure has the</p> <p>10 potential to cause that inflammatory response,</p> <p>11 and then the time, scale, and magnitude of that</p> <p>12 response is going to vary by person. Therefore,</p> <p>13 I would expect there would be a variability in</p> <p>14 individuals exposed to talc.</p> <p>15 MS. BROWN:</p> <p>16 Q Uh-huh. Is your opinion related to all</p> <p>17 the different histologic types of epithelial</p> <p>18 ovarian cancer?</p> <p>19 A My -- my opinion is not exclusive to</p> <p>20 any -- any one type. Certainly, the epithelial</p> <p>21 serous being the more common and most virulent</p> <p>22 type of cancers I think represents the most</p> <p>23 common.</p> <p>24 From a mechanistic perspective, I</p>	<p style="text-align: right;">Page 261</p> <p>1 in -- in disease progression.</p> <p>2 Q So when you conclude, as you do in your</p> <p>3 report, that talcum powder products cause chronic</p> <p>4 inflammation, you do not conclude that that</p> <p>5 chronic inflammation causes ovarian cancer?</p> <p>6 MS. O'DELL:</p> <p>7 Object to the form.</p> <p>8 A I wasn't asked to provide a causation.</p> <p>9 MS. BROWN:</p> <p>10 Q Your opinion here is limited to the</p> <p>11 potential for talcum powder products to produce</p> <p>12 inflammation; correct?</p> <p>13 MS. O'DELL:</p> <p>14 Object to the form.</p> <p>15 A No. My -- so my opinion is a -- is a</p> <p>16 supported plausible biological mechanism by which</p> <p>17 the exposure to talc can lead to ovarian cancer.</p> <p>18 And, in my opinion, as supported in the -- in the</p> <p>19 report, that is through an inflammatory response.</p> <p>20 MS. BROWN:</p> <p>21 Q I must be missing you, Doctor. So are</p> <p>22 you of the opinion that inflammation can cause</p> <p>23 ovarian cancer?</p> <p>24 A I'm of the opinion that inflammation is</p>

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<p style="text-align: right;">Page 262</p> <p>1 a component of ovarian cancer.</p> <p>2 Q Well, I'm not sure what you mean by</p> <p>3 that. Can inflammation cause ovarian cancer?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form. Asked and</p> <p>6 answered.</p> <p>7 A I'm asked -- I suppose -- again, the</p> <p>8 opinion here is of a mechanistic opinion, not a</p> <p>9 causation. I would defer to some of the</p> <p>10 epidemiology experts to have opinions on</p> <p>11 causation.</p> <p>12 MS. BROWN:</p> <p>13 Q You don't have an opinion on whether or</p> <p>14 not inflammation can cause ovarian cancer?</p> <p>15 MS. O'DELL:</p> <p>16 Different question.</p> <p>17 A Correct. That's a --</p> <p>18 As we've been discussing, my opinions</p> <p>19 are that inflammation is a component of ovarian</p> <p>20 cancer and can be attributed to aspects, not</p> <p>21 exclusively, but contributing to aspects of its</p> <p>22 initiation and aspects of its progression. But I</p> <p>23 did not say that ovarian cancer is caused by</p> <p>24 inflammation.</p>	<p style="text-align: right;">Page 264</p> <p>1 Well, first, we're -- I want to be</p> <p>2 cautious with our use of the word "cause"</p> <p>3 and -- because that's, as we've been discussing,</p> <p>4 this is a -- it is -- it is not controversial</p> <p>5 that ovarian cancer -- inflammation plays a role</p> <p>6 in ovarian cancer and -- and, again, my opinion</p> <p>7 is not towards causation.</p> <p>8 MS. BROWN:</p> <p>9 Q Well, I mean, tumors themselves elicit</p> <p>10 inflammatory responses; right?</p> <p>11 A What -- so what -- specifically, what</p> <p>12 are you referring to?</p> <p>13 Q Well, you talk about tumor-activated</p> <p>14 macrophages in your report; right?</p> <p>15 A Yes.</p> <p>16 Q There is an inflammatory response</p> <p>17 that's produced by the tumor itself; correct?</p> <p>18 A Yes. There are -- there -- there --</p> <p>19 there are absolutely cancer progression markers</p> <p>20 that are associated with continued inflammation.</p> <p>21 Q And that has nothing to do necessarily</p> <p>22 with the events that cause the cancer. Right?</p> <p>23 MS. O'DELL:</p> <p>24 Object to the form.</p>
<p style="text-align: right;">Page 263</p> <p>1 MS. BROWN:</p> <p>2 Q And what scientific support do you have</p> <p>3 for your opinion that inflammation is a component</p> <p>4 of ovarian cancer and can be attributed to</p> <p>5 aspects of ovarian cancer, including its</p> <p>6 initiation?</p> <p>7 A So, again, the synthesis of the -- of</p> <p>8 the papers we've been discussing, including Saed</p> <p>9 and others, showing the reactive oxygen species</p> <p>10 produced from talc. And, then, as far as</p> <p>11 inflammation and its role in cancer, there</p> <p>12 are -- and it's a fundamentally accepted aspect</p> <p>13 of cancer biology that's been around for -- for</p> <p>14 quite some time. And we mentioned earlier that</p> <p>15 there's a variety of review articles, including</p> <p>16 the ones we were comparing sentences to earlier</p> <p>17 today, that describe that in great detail.</p> <p>18 Q It's not generally accepted, though,</p> <p>19 that ovarian cancer is caused by inflammation.</p> <p>20 Fair?</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form.</p> <p>23 A I think there's a number of studies</p> <p>24 that --</p>	<p style="text-align: right;">Page 265</p> <p>1 A Well, so the -- we -- we would be going</p> <p>2 down a slightly different road. And if</p> <p>3 we're -- so cancer as a complex disorder, you</p> <p>4 know, begins with an initiating event. But there</p> <p>5 is -- there is absolutely tumor evolution from</p> <p>6 that initial event through the progression of the</p> <p>7 disease.</p> <p>8 So to state that the -- in the initial</p> <p>9 inflammatory response to the tumor is -- is not</p> <p>10 causative to the continuation of the disease I</p> <p>11 think would be incorrect.</p> <p>12 MS. BROWN:</p> <p>13 Q The Penninkilampi authors -- to</p> <p>14 conclude our discussion here -- concluded that</p> <p>15 the paragraph you were looking at with the</p> <p>16 sentence "The potential mechanism by which</p> <p>17 genital talc is associated with an increased risk</p> <p>18 of ovarian cancer, hence, remains unclear," do</p> <p>19 you see that?</p> <p>20 A Yes.</p> <p>21 Q And this meta-analysis was published in</p> <p>22 January of 2018; correct?</p> <p>23 A Correct.</p> <p>24 Q And it is, in fact, cited in the</p>

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<p style="text-align: right;">Page 266</p> <p>1 majority of the plaintiff expert reports in this 2 litigation. Did you see that? 3 MS. O'DELL: 4 Object to the form. If you know that. 5 Don't speculate. 6 MS. BROWN: 7 Q That's why I asked "Did you see that?" 8 A So I didn't specifically look at if 9 this was referenced. I -- I certainly referenced 10 it. But I would also point out another important 11 part of the -- of this same reference, a -- about 12 halfway down the following paragraph, beginning 13 with "If chronic inflammation due to ascending 14 foreign bodies is indeed the mechanism by which 15 talc use is associated with ovarian cancer risks, 16 then these results fit the picture." 17 So I think the authors were both 18 describing some things that remain unclear but 19 also offering some comments that are supportive 20 of our earlier discussions today on this 21 mechanism. 22 Q And your opinion here today, Doctor, is 23 limited to the potential mechanism; right? 24 MS. O'DELL:</p>	<p style="text-align: right;">Page 268</p> <p>1 available data that there is a biologically 2 plausible mechanism surrounding and, indeed, in 3 the previous paragraph at the end of it where 4 they discuss use of -- or expression of 5 cyclooxygenase 1 and 2 as well as the action of 6 NSAIDs, again, supportive of -- somewhat 7 supportive of the inflammatory model. But... 8 MS. BROWN: 9 Q Well, as it relates to the NSAIDs, 10 Doctor, they point to the fact that the NSAID 11 data is inconsistent, at best, as evidence 12 supportive of their conclusions that the 13 mechanism is unclear; right? 14 A No. They point to it as -- they 15 actually try to clarify that the -- the seemingly 16 contradictory data regarding the NSAID use can be 17 explained by the relatively low expression of 18 cyclooxygenase 1 and cyclooxygenase 2, which are 19 the targets of most common NSAIDs. 20 Q What they say is that the use of 21 nonsteroidal anti-inflammatory drugs, NSAIDs, is 22 not inversely associated with the incidence of 23 ovarian cancer as may be expected if the etiology 24 was related to chronic inflammation. Right?</p>
<p style="text-align: right;">Page 267</p> <p>1 Object to the form. 2 A So my -- my opinion is -- is -- is 3 regarding a biologically plausible mechanism. 4 But, then -- and, in doing so, have reviewed some 5 of these studies that we're discussing now. 6 MS. BROWN: 7 Q Good. 8 And, as it relates to that potential 9 mechanism, these Penninkilampi authors conclude 10 that the potential mechanism remains unclear. 11 Right? 12 MS. O'DELL: 13 Objection to form. 14 A They -- the article makes a statement, 15 "The potential mechanism by which genital talc is 16 associated with an increased risk of ovarian 17 cancer, hence, remains unclear." 18 However, as we've been discussing, they 19 go on to state, "If chronic inflammation due to 20 ascending foreign body is indeed the mechanism," 21 then there -- the results in this paper 22 are -- fit that model. 23 So I think they're making reason- -- 24 making reasonable statements based on the</p>	<p style="text-align: right;">Page 269</p> <p>1 MS. O'DELL: 2 Objection to form. 3 A Yes, that statement is made. But, 4 importantly, it is incomplete without the next 5 sentence, again, explaining that -- that 6 apparent -- that apparent question. 7 So if the -- if NSAIDs are not 8 effective in ovarian cancer and the -- and, in 9 turn -- and if the observation is also made that 10 ovarian cancer cells don't express cyclooxygenase 11 1 and 2, then they would not -- they would be 12 nonresponsive to NSAIDs. 13 Q You state on page 12 of your report, 14 Doctor, in the last paragraph, the second-to-last 15 sentence that begins "moreover," that the effect 16 of nonsteroidal anti-inflammatory drugs, NSAIDs, 17 to reduce the risk of ovarian cancer provides 18 additional support for what you're discussing 19 here, which is that chronic inflammation plays a 20 key role in the development of ovarian cancer. 21 Right? 22 A Correct. 23 Q And that is, in fact, the opposite of 24 what the authors in Penninkilampi report as</p>

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<p>1 relates to NSAIDs; right?</p> <p>2 MS. O'DELL:</p> <p>3 Object to the form.</p> <p>4 A Not -- not necessarily. So there's --</p> <p>5 getting back to the -- the specific cells under</p> <p>6 question and the inflammatory response being</p> <p>7 examined. And, so, if we are lowering overall</p> <p>8 chronic inflammation through the use of an NSAID</p> <p>9 is -- is one question. A separate question is is</p> <p>10 a -- is a ovarian cancer cell responsive to</p> <p>11 NSAIDs. So they're two separate biological</p> <p>12 phenomenon.</p> <p>13 And, in one case, if those cells are</p> <p>14 not expressing the cyclooxygenase 1 and 2,</p> <p>15 they'll be nonresponsive.</p> <p>16 I would speculate that NSAID use in the</p> <p>17 rest of the body would still result in the</p> <p>18 expected effect due to, you know, the -- due to</p> <p>19 the inhibition of cyclooxygenase 1 and 2.</p> <p>20 So I don't think they're necessarily in</p> <p>21 conflict with each other.</p> <p>22 (DEPOSITION EXHIBIT NUMBER 20</p> <p>23 WAS MARKED FOR IDENTIFICATION.)</p> <p>24 MS. BROWN:</p>	<p>1 statement.</p> <p>2 And then there was, I think,</p> <p>3 importantly, the Lin 2011 paper is also relevant.</p> <p>4 Q Well, as it relates to the Merritt</p> <p>5 paper, this cite is wrong; right?</p> <p>6 A I need a moment to --</p> <p>7 Q Let's look at what Merritt actually</p> <p>8 found about pelvic inflammatory disease.</p> <p>9 If you look --</p> <p>10 MS. O'DELL:</p> <p>11 If you need a moment --</p> <p>12 Excuse me. I'm sorry. I didn't mean</p> <p>13 to interrupt you.</p> <p>14 If you need a moment to refresh</p> <p>15 yourself, Dr. Levy, please do.</p> <p>16 MS. BROWN:</p> <p>17 Q Sure. And if you -- when you're ready,</p> <p>18 Doctor, I'll direct you to the second column on</p> <p>19 page 174, and I want to talk about the last</p> <p>20 paragraph there that begins "if inflammation."</p> <p>21 A Page?</p> <p>22 Q And I'll read it into the record while</p> <p>23 you orient yourself. It's page 174, right-hand</p> <p>24 column. Final paragraph states, "If inflammation</p>
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<p>1 Q Handing you what we've marked as</p> <p>2 Defense Exhibit 20 to your deposition, this is a</p> <p>3 paper by Merritt entitled "Talcum Powder Chronic</p> <p>4 Pelvic Inflammation and NSAIDs in Relation to the</p> <p>5 Risk of Epithelial Ovarian Cancer."</p> <p>6 Do you see that?</p> <p>7 A I do.</p> <p>8 Q And, in fact, on page 12 of your</p> <p>9 report, you cite this Merritt article. Correct?</p> <p>10 A Yes. Uh-huh.</p> <p>11 Q And you cite it for the proposition</p> <p>12 that studies have found a relationship between</p> <p>13 pelvic inflammatory disease and ovarian cancer</p> <p>14 risk. Correct?</p> <p>15 A Correct.</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 MS. BROWN:</p> <p>19 Q And you point to Merritt when you</p> <p>20 determine here as a finding of a relationship</p> <p>21 between pelvic inflammatory disease and ovarian</p> <p>22 cancer in support of your opinion that</p> <p>23 inflammation can cause ovarian cancer. True?</p> <p>24 A I'd have to double-check that</p>	<p>1 plays a role in the etiology of ovarian cancer,</p> <p>2 then it would be expected that PID would be</p> <p>3 associated with increased risks of ovarian</p> <p>4 cancer. PID is not associated with elevated risk</p> <p>5 of ovarian tumors in our data, confirming several</p> <p>6 previous reports of no association with PID in</p> <p>7 studies of all subtypes of ovarian cancer."</p> <p>8 Did I read that correctly?</p> <p>9 A You did.</p> <p>10 Q All right. So you cited this study for</p> <p>11 the proposition that studies have found a</p> <p>12 relationship between PID and ovarian cancer risk.</p> <p>13 Right?</p> <p>14 A No. I said -- I cited -- I said</p> <p>15 studies have found a relationship, yes, between</p> <p>16 PID and ovarian cancer risk.</p> <p>17 Q And, in fact, this study did not find a</p> <p>18 relationship between PID and ovarian cancer risk.</p> <p>19 Right?</p> <p>20 A I think this study found a -- I'm just</p> <p>21 looking at the...</p> <p>22 So -- I'm sorry. Would you ask your</p> <p>23 question again? This -- this study did not</p> <p>24 find your --</p>

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<p>1 Yes, I --</p> <p>2 Q Sure. I just -- you cited this study</p> <p>3 for the proposition that it showed there was a</p> <p>4 relationship between pelvic inflammatory disease</p> <p>5 and ovarian cancer risk, but, in fact, the study</p> <p>6 showed the opposite. Correct?</p> <p>7 A Well, to be clear on the wording,</p> <p>8 stated that the studies have found a</p> <p>9 relationship. I didn't indicate whether it was</p> <p>10 positive or negative.</p> <p>11 But I think, importantly, the study</p> <p>12 also has an important paragraph that is probably</p> <p>13 more related to its inclusion, which is on the</p> <p>14 same page we were just on, 174, second full</p> <p>15 paragraph in the discussion.</p> <p>16 Q One of the things on this page,</p> <p>17 Doctor --</p> <p>18 MS. O'DELL:</p> <p>19 Are you finished, Doctor?</p> <p>20 A I think important to at least finish</p> <p>21 that thought.</p> <p>22 That paragraph reads, "Focusing on talc</p> <p>23 use, we found that any use of perineal talc was</p> <p>24 associated with a small but significantly</p>	<p>1 quote, "We conclude that, on balance, chronic</p> <p>2 inflammation does not play a major role in the</p> <p>3 development of ovarian cancer."</p> <p>4 Q Do you see that, Doctor?</p> <p>5 A I see that.</p> <p>6 Q And what this study did was it</p> <p>7 endeavored to look into factors potentially</p> <p>8 associated with ovarian inflammation to see if it</p> <p>9 could support the theory that chronic</p> <p>10 inflammation plays a role in ovarian cancer;</p> <p>11 right?</p> <p>12 MS. O'DELL:</p> <p>13 Object to the form.</p> <p>14 A I would need to -- this one limitation</p> <p>15 of this particular paper is that it is connecting</p> <p>16 inflammation as evidenced by pelvic inflammatory</p> <p>17 disease and assuming that that source and type of</p> <p>18 inflammation would be -- the fact that there's</p> <p>19 not a direct association between -- or an</p> <p>20 increased risk of ovarian cancer in the presence</p> <p>21 of pelvic inflammatory disease; therefore,</p> <p>22 inflammation must not play a role in ovarian</p> <p>23 cancer. So that is their conclusions.</p> <p>24 MS. BROWN:</p>
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<p>1 increased risk of ovarian cancer overall and</p> <p>2 specifically amongst the invasive and LNP serous</p> <p>3 tumors, although no clear dose response with</p> <p>4 increase in duration of use was identified. This</p> <p>5 finding is consistent with results of previous</p> <p>6 studies."</p> <p>7 So in the case of the report and the</p> <p>8 biologically plausible mechanism that's been</p> <p>9 supported by these studies, these studies</p> <p>10 differentiating the process of pelvic</p> <p>11 inflammatory disease doesn't ex- -- doesn't</p> <p>12 exclude or refute the inflammatory role or the</p> <p>13 role inflammation may play in ovarian cancer.</p> <p>14 Q What this study concludes is that, on</p> <p>15 balance, chronic inflammation does not play a</p> <p>16 major role in the development of ovarian cancer.</p> <p>17 Do you recall reviewing this in connection with</p> <p>18 your opinions in this case?</p> <p>19 MS. O'DELL:</p> <p>20 Object to the form. Misstates the</p> <p>21 exhibit.</p> <p>22 MS. BROWN:</p> <p>23 Counsel, I'll direct you to the last</p> <p>24 paragraph of the abstract on page 1 which reads,</p>	<p>1 Q Well, they looked at a bunch of</p> <p>2 different inflammatory conditions, didn't they?</p> <p>3 That was the focus of the study. The authors</p> <p>4 endeavored to look at a number of different</p> <p>5 pro-inflammatory factors and see if they</p> <p>6 influenced ovarian cancer. Do you recall</p> <p>7 reviewing that?</p> <p>8 A I do. I think -- but, more</p> <p>9 importantly, when we look at the -- their</p> <p>10 specific statements that are surrounding the</p> <p>11 mechanism we're discussing today, which has to do</p> <p>12 with talc exposure and perineal talc use, I think</p> <p>13 their -- their statements in that sense, which</p> <p>14 have already been read, quite stand on their own.</p> <p>15 So what this may indicate is a variety</p> <p>16 of types of inflammation do -- as present in</p> <p>17 other diseases, those individually do not or may</p> <p>18 not have a specific role in the progression of</p> <p>19 ovarian cancer.</p> <p>20 But it does not -- again, it does not</p> <p>21 mean that ovarian inflammation at the site of</p> <p>22 talc exposure in the ovary can't have a role in</p> <p>23 the progression of disease where -- again, as we</p> <p>24 were discussing earlier, with inflammation, we're</p>

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<p style="text-align: right;">Page 278</p> <p>1 now connecting independent biological processes.</p> <p>2 And I think you're -- I want to be sure</p> <p>3 we're clear and not drawing the use of the word</p> <p>4 "chronic inflammation" as meaning any</p> <p>5 inflammation and, therefore, if it's not</p> <p>6 associated with ovarian cancer, that inflammation</p> <p>7 can't have a role.</p> <p>8 What we're speaking about in terms of</p> <p>9 this mechanism is inflammation caused by the</p> <p>10 perineal use of talcum powder in the ovary and</p> <p>11 the -- and the -- to explain that increased risk</p> <p>12 of ovarian cancer, what is a plausible mechanism.</p> <p>13 Q The authors write, on page 74 -- 174,</p> <p>14 Doctor, second column, paragraph that begins with</p> <p>15 "It has been hypothesized," "It has been</p> <p>16 hypothesized that talc is linked to ovarian</p> <p>17 cancer development through inflammation," comma,</p> <p>18 "however evidence linking an inflammatory</p> <p>19 response with talc contamination of the ovaries</p> <p>20 is lacking."</p> <p>21 Do you see that?</p> <p>22 A I do.</p> <p>23 Q And you disagree with that statement?</p> <p>24 A I would -- I would suggest that a</p>	<p style="text-align: right;">Page 280</p> <p>1 couple times, and that's a 1.17 relative risk</p> <p>2 that you're referring to. Is that right?</p> <p>3 A Where is that?</p> <p>4 Q I'm looking at -- in the abstract.</p> <p>5 A Yes.</p> <p>6 Q Right. And the confidence interval is</p> <p>7 1.01 to 1.36. Right?</p> <p>8 A Correct.</p> <p>9 MS. O'DELL:</p> <p>10 As to what finding?</p> <p>11 MS. BROWN:</p> <p>12 The one we're discussing.</p> <p>13 Q And, Doctor, you know that one -- a</p> <p>14 confidence interval that begins with one is not</p> <p>15 statistically significant?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 MS. BROWN:</p> <p>19 Q Did you know that?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form.</p> <p>22 A Well, I would say the authors have</p> <p>23 stated in that abstract that it is statistically</p> <p>24 significant.</p>
<p style="text-align: right;">Page 279</p> <p>1 number of studies in the literature since the</p> <p>2 publication of this paper would -- would suggest</p> <p>3 that these conclusions may have been premature.</p> <p>4 Q Do you think that, at the time this</p> <p>5 paper was published in 2008, that Merritt was</p> <p>6 accurately representing the data as it related to</p> <p>7 whether chronic inflammation could play a role in</p> <p>8 the development of ovarian cancer?</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form.</p> <p>11 A I would say that Merritt has an</p> <p>12 unresolved -- has a number of unresolved</p> <p>13 conclusions or partial conclusions in their</p> <p>14 paper, again, including the paragraph we've</p> <p>15 discussed where they comment on the talc use with</p> <p>16 an increased risk of ovarian cancer.</p> <p>17 MS. BROWN:</p> <p>18 Q Did you see the confidence interval on</p> <p>19 that finding, Doctor?</p> <p>20 A I'd have to -- in --</p> <p>21 Is this in this paper or in the number</p> <p>22 of the --</p> <p>23 Q You reference the finding of an</p> <p>24 association between talc use and ovarian cancer a</p>	<p style="text-align: right;">Page 281</p> <p>1 MS. BROWN:</p> <p>2 Q Sure, because it's 1.01. My question</p> <p>3 to you was do you know that a confidence interval</p> <p>4 that begins with one is not statistically</p> <p>5 significant?</p> <p>6 This finding, Doctor, is barely</p> <p>7 statistically significant, isn't it?</p> <p>8 MS. O'DELL:</p> <p>9 Object to the form.</p> <p>10 A Again -- again, it's a -- whether it's</p> <p>11 barely or whether it's tremendously statistically</p> <p>12 significant, it -- it's still a finding that I</p> <p>13 would say is in support of -- has been supported</p> <p>14 by other studies with similar relative risk</p> <p>15 numbers in the -- in the 1.2 range and above, as</p> <p>16 indicated.</p> <p>17 MS. BROWN:</p> <p>18 Q Finally, Doctor, at the very -- the</p> <p>19 very last sentence of this Merritt study we're</p> <p>20 discussing, on page 175, concludes, "However,</p> <p>21 experimental evidence that perineal talc use</p> <p>22 elicits an inflammatory response in the ovaries</p> <p>23 is lacking, and overall we conclude that chronic</p> <p>24 inflammation does not play a major role in the</p>

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<p style="text-align: right;">Page 282</p> <p>1 development of ovarian cancer."</p> <p>2 And my question for you is what</p> <p>3 methodology did you employ to consider the</p> <p>4 findings of the Merritt paper in coming to your</p> <p>5 opinions contained in your report?</p> <p>6 MS. O'DELL:</p> <p>7 Object to the form.</p> <p>8 A Again, as we've discussed earlier here</p> <p>9 today, the -- there's been no singular paper that</p> <p>10 had a specific role in -- in developing the</p> <p>11 biologically plausible mechanism contained in the</p> <p>12 report. And, so, this -- this paper, among many</p> <p>13 others, was -- was used.</p> <p>14 MS. BROWN:</p> <p>15 Q Right. But the findings of this paper</p> <p>16 is that talcum powder doesn't produce an</p> <p>17 inflammatory response that leads to cancer.</p> <p>18 Right?</p> <p>19 A The -- the findings of this paper was</p> <p>20 that there's not an association of pelvic</p> <p>21 inflammatory disease and risk of ovar- -- of</p> <p>22 epithelial ovarian cancer.</p> <p>23 Q They conclude that chronic inflammation</p> <p>24 doesn't play a role in the development of ovarian</p>	<p style="text-align: right;">Page 284</p> <p>1 Again, the observations in this paper</p> <p>2 are regarding chronic inflammation and its -- and</p> <p>3 its major role in the development of ovarian</p> <p>4 cancer; and, again, in this -- in the specific</p> <p>5 individuals that they've looked at, it's in</p> <p>6 regards to pelvic inflammatory disease.</p> <p>7 And, so, as far as weighting that</p> <p>8 paper, it would be similar to other papers and</p> <p>9 other observations in the sense that it was --</p> <p>10 that the mechanism that is supported by a wide</p> <p>11 variety of work considers a history of -- history</p> <p>12 of work in the talc, inflammation, and ovarian</p> <p>13 cancer fields both in basic research and</p> <p>14 epidemiology to come up -- to come to the</p> <p>15 conclusions and mechanisms that are proposed.</p> <p>16 I don't -- I can't give you a specific</p> <p>17 weighting algorithm that was used on any -- any</p> <p>18 given paper.</p> <p>19 MS. BROWN:</p> <p>20 Q Did you consider Merritt's finding that</p> <p>21 evidence linking an inflammatory response with</p> <p>22 talc of the ovaries is lacking?</p> <p>23 A I certainly considered their -- I</p> <p>24 considered their statements in the -- in the</p>
<p style="text-align: right;">Page 283</p> <p>1 cancer; right?</p> <p>2 A I think they've -- they've extended</p> <p>3 that observation regarding pelvic inflammatory</p> <p>4 disease to that conclusion.</p> <p>5 But I think the studies that have come</p> <p>6 after this and other -- certainly other areas of</p> <p>7 review would suggest that those specific -- the</p> <p>8 wording of those specific statements may not be</p> <p>9 the most appropriate representation of the -- of</p> <p>10 the observations made in the -- in the Merritt</p> <p>11 paper.</p> <p>12 Q So did you weight the Merritt paper</p> <p>13 less than some other papers that came after it?</p> <p>14 Or how did you --</p> <p>15 What I'm trying to understand is your</p> <p>16 methodology for considering this paper, which</p> <p>17 seems to squarely conclude talc doesn't cause</p> <p>18 inflammation.</p> <p>19 MS. O'DELL:</p> <p>20 Object to the form.</p> <p>21 A I'm not -- so I would -- I would</p> <p>22 disagree that -- this paper does not make those</p> <p>23 conclusions that talc does not cause</p> <p>24 inflammation. What they --</p>	<p style="text-align: right;">Page 285</p> <p>1 paper. And I would question the dichotomy of</p> <p>2 the -- of some of their statements regarding talc</p> <p>3 risk to cancer.</p> <p>4 And the first question that would come</p> <p>5 to mind for this particular study is how they</p> <p>6 assessed talc-related inflammation in --</p> <p>7 specifically in the ovary. I don't recall seeing</p> <p>8 how they made that assessment.</p> <p>9 It, instead, seemed to me that their</p> <p>10 assessments were based on chronic inflammation as</p> <p>11 it related to other biological conditions and</p> <p>12 then extrapolating that to rate of ovarian</p> <p>13 cancer.</p> <p>14 Q How do you think one should measure</p> <p>15 talc-related inflammation in the ovary?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A Again, I wasn't asked to -- to provide</p> <p>19 that opinion. But I would reference the more</p> <p>20 recent Saed paper which -- and other molecular --</p> <p>21 and other molecular studies and certainly defer</p> <p>22 to Dr. Saed as an expert witness to discuss</p> <p>23 appropriate measurements for talc-related</p> <p>24 inflammation in the -- in the ovary or ovarian</p>

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<p style="text-align: right;">Page 286</p> <p>1 cells.</p> <p>2 MS. BROWN:</p> <p>3 Q Have you spoken with Dr. Saed?</p> <p>4 A I have not.</p> <p>5 Q Have you requested any information from</p> <p>6 Dr. Saed?</p> <p>7 A No, I have not.</p> <p>8 Q Have you -- would you hold to the same</p> <p>9 opinion if you did not consider the work of</p> <p>10 Dr. Saed?</p> <p>11 MS. O'DELL:</p> <p>12 Objection to form. Vague.</p> <p>13 A I -- the work of Dr. Saed is -- is a</p> <p>14 consideration among the wide variety of other</p> <p>15 literature contained in here. And Dr. Saed's</p> <p>16 work for in vitro analysis and the quantitation</p> <p>17 of specific reactive oxygen species is -- is a</p> <p>18 factor in and it is in support of the mechanism</p> <p>19 that I've proposed, which is that that mechanism</p> <p>20 does not rely on that study or any singular study</p> <p>21 for it to be valid.</p> <p>22 MS. BROWN:</p> <p>23 Q The mechanism you proposed, Doctor, is</p> <p>24 not yet generally accepted in the scientific</p>	<p style="text-align: right;">Page 288</p> <p>1 biologically plausible mechanism that was also</p> <p>2 peer-reviewed, and I would rely on or point you</p> <p>3 to a number of other expert reports, particularly</p> <p>4 in the epidemiology space from this case, where</p> <p>5 you'll find a great many parallels to -- to this</p> <p>6 case.</p> <p>7 So I, instead, would state</p> <p>8 independently myself and other respected</p> <p>9 scientists have essentially developed the same</p> <p>10 opinions regarding mechanism in this -- in this</p> <p>11 particular space.</p> <p>12 MS. BROWN:</p> <p>13 Q Is there another plaintiffs' expert</p> <p>14 that you're aware of who holds the same opinion</p> <p>15 as you do on biological plausibility?</p> <p>16 A Yes.</p> <p>17 Q Who's that?</p> <p>18 A Patricia Moorman, who is an</p> <p>19 epidemiologist whose report I had the opportunity</p> <p>20 to read yesterday.</p> <p>21 Q Is there -- and -- and even though</p> <p>22 she's an epidemiologist, Dr. Moorman has a view</p> <p>23 on biological plausibility? Is that right?</p> <p>24 MS. O'DELL:</p>
<p style="text-align: right;">Page 287</p> <p>1 community. Would you agree?</p> <p>2 MS. O'DELL:</p> <p>3 Object to the form.</p> <p>4 A I wouldn't have a basis for that</p> <p>5 opinion. As -- as we talked about earlier, I</p> <p>6 haven't shared this mechanism to ask for that</p> <p>7 opinion.</p> <p>8 MS. BROWN:</p> <p>9 Q You haven't published the proposed</p> <p>10 mechanism that is the subject of your report. Is</p> <p>11 that right?</p> <p>12 A That's right.</p> <p>13 Q You haven't discussed the proposed</p> <p>14 mechanism that is the subject of your report with</p> <p>15 any of your colleagues at HudsonAlpha; correct?</p> <p>16 A That's correct.</p> <p>17 Q So whether or not the proposed</p> <p>18 mechanism that is the subject of your report</p> <p>19 would be accepted by your peers in the scientific</p> <p>20 community, that's not something you have yet</p> <p>21 evaluated; correct?</p> <p>22 MS. O'DELL:</p> <p>23 Object to the form.</p> <p>24 A My -- I wasn't requested to provide a</p>	<p style="text-align: right;">Page 289</p> <p>1 Object to the form.</p> <p>2 A She has a view on --</p> <p>3 In her report was a -- a view on</p> <p>4 mechanism -- on mechanism, which included the</p> <p>5 discussion of inflammatory response and its role</p> <p>6 in ovarian cancer, which parallels this report.</p> <p>7 MS. BROWN:</p> <p>8 Q Do you consider your proposed mechanism</p> <p>9 that is the subject of your report to be a novel</p> <p>10 concept in the scientific world?</p> <p>11 MS. O'DELL:</p> <p>12 Object to the form.</p> <p>13 A Which part?</p> <p>14 MS. BROWN:</p> <p>15 Q Any part.</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A Again, I -- my -- the -- what was</p> <p>19 requested of me was not to develop a novel</p> <p>20 concept or even to describe an untested</p> <p>21 hypothesis. What was requested of me was to</p> <p>22 review the available literature and provide a</p> <p>23 biologically plausible mechanism for talc</p> <p>24 exposure to ovarian cancer. And, so, that's</p>

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<p>1 what -- that's what my report provides.</p> <p>2 MS. BROWN:</p> <p>3 Q Do you think there could be other</p> <p>4 biologically plausible mechanisms by which talcum</p> <p>5 powder would be associated with ovarian cancer?</p> <p>6 A I haven't been asked to -- to make a</p> <p>7 review related to other biological mechanisms. I</p> <p>8 was asked to develop a biologically plausible</p> <p>9 mechanism. And upon review of the totality of</p> <p>10 the literature, this mechanism that -- that I've</p> <p>11 presented and provided in the report is, in my</p> <p>12 opinion, the correct mechanism.</p> <p>13 Q Did you have complete autonomy in your</p> <p>14 task to develop a biologically plausible</p> <p>15 mechanism?</p> <p>16 A Yes.</p> <p>17 Q Were there any limitations on how you</p> <p>18 should go about developing this biologically</p> <p>19 plausible limita- -- mechanism?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form of the question to</p> <p>22 the degree that the question seeks --</p> <p>23 MS. BROWN:</p> <p>24 Form.</p>	<p>1 for you here, Doctor, is, were -- was there any</p> <p>2 limitation placed on you that you relied on in</p> <p>3 trying to develop your biologically plausible</p> <p>4 mechanism?</p> <p>5 MS. O'DELL:</p> <p>6 What's allowed -- you're well aware of</p> <p>7 this, counsel, I know -- that what's discoverable</p> <p>8 is are there materials considered -- you can ask</p> <p>9 him that -- was there assumptions that he was</p> <p>10 asked to make -- that's discoverable -- and the</p> <p>11 compensation. Those are the three things. Not</p> <p>12 conversations between counsel and Dr. Levy.</p> <p>13 So --</p> <p>14 MS. BROWN:</p> <p>15 Counsel, you can instruct or we'll get</p> <p>16 the judge. We do not have time for your</p> <p>17 speeches. We're trying to finish up and let</p> <p>18 other people -- other people ask questions.</p> <p>19 MS. O'DELL:</p> <p>20 That's straight from the rules. You're</p> <p>21 well aware of that.</p> <p>22 MS. BROWN:</p> <p>23 So here's the question. If you want to</p> <p>24 instruct, we'll take a break and get the judge.</p>
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<p>1 MS. O'DELL:</p> <p>2 No, no. If it goes to conversations</p> <p>3 with counsel, it is not form. It is</p> <p>4 attorney-client privilege and it's protected.</p> <p>5 Work product privilege is protected.</p> <p>6 And, so, Dr. Levy --</p> <p>7 MS. BROWN:</p> <p>8 No. Counsel --</p> <p>9 MS. O'DELL:</p> <p>10 Excuse me. Excuse me. I'm directing</p> <p>11 my witness based on privilege, and I can do that.</p> <p>12 To the degree that counsel is trying to</p> <p>13 seek the substance of discussions you had with</p> <p>14 counsel, those are protected, and I direct you</p> <p>15 not to answer.</p> <p>16 To the degree there's something in your</p> <p>17 mind to respond that's not that, you may -- you</p> <p>18 may respond.</p> <p>19 MS. BROWN:</p> <p>20 Q And as -- as counsel well knows,</p> <p>21 because we've had this discussion earlier this</p> <p>22 week, the federal rules allow discovery of any</p> <p>23 material you relied on in forming your opinions.</p> <p>24 And, so, my answer here -- my question</p>	<p>1 Q Did you rely on any instruction from</p> <p>2 counsel regarding any limitations on how you were</p> <p>3 to attempt to develop your biologically plausible</p> <p>4 mechanism?</p> <p>5 A No. I was -- I was not provided --</p> <p>6 there were no --</p> <p>7 I'm trying to make sure I answer to be</p> <p>8 correct. But my very simple and direct answer is</p> <p>9 the requests for the report were very succinct</p> <p>10 and were given without limitation.</p> <p>11 Q Did you try to develop any mechanism</p> <p>12 that you rejected in connection with your report?</p> <p>13 MS. O'DELL:</p> <p>14 Object to the form. Vague.</p> <p>15 A So I would best answer that by saying I</p> <p>16 did not develop an initial mechanism and,</p> <p>17 instead, began a literature review looking at the</p> <p>18 available literature in talcum powder</p> <p>19 inflammation in cancer, ovarian cancer, and then</p> <p>20 in related subjects, and then, through the course</p> <p>21 of that review, was able to synthesize the</p> <p>22 opinion that you have, that we've been</p> <p>23 discussing, in the report.</p> <p>24 MS. BROWN:</p>

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<p>1 Q Do you consider the biologically 2 plausible mechanism that is the subject of your 3 report to be a hypothesis? 4 MS. O'DELL: 5 Object to the form. Asked and 6 answered. 7 A No, no. In fact, it is not. And 8 it's -- I think it's very fundamentally different 9 than a hypothesis. 10 Because, again, to state, the 11 activities that were undertaken was a review of 12 the literature and then, based on that review, a 13 mechanism that was biologically plausible. It is 14 not hypothetical. 15 MS. BROWN: 16 Q Have you tested your biologically 17 plausible mechanism? 18 MS. O'DELL: 19 Object to the form. 20 A Tested in the sense of -- 21 So I would -- I would answer that as -- 22 in -- in my opinion, I would suggest that this 23 has been tested based on following the completion 24 of the report and reading other similarly derived</p>	<p>1 mechanism, you mean other experts in this 2 litigation? 3 MS. O'DELL: 4 Object to the form. Misstates his 5 testimony. 6 A Other -- other material -- the 7 materials that I was -- that I was provided. 8 MS. BROWN: 9 Q And those materials are in the form of 10 other expert reports like yours; right? 11 MS. O'DELL: 12 Object to the form. 13 A They are. 14 MS. BROWN: 15 Q Are you aware of any nonlitigation 16 expert that has arrived at the same biologically 17 plausible proposed mechanism as you? 18 MS. O'DELL: 19 Object to the form. 20 A Well, I think -- yeah, in the sense -- 21 in the sense of the number of publications we've 22 been discussing and some of the more recent both 23 reviews and -- and Saed's paper, I suppose, as 24 we've been discussing, Dr. Saed has been funded</p>
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<p>1 or similarly requested both literature, some of 2 the publications that we've been discussing, as 3 well as other expert reports that have, as we've 4 just discussed, some parallel aspects. 5 So, from a formal scientific process, 6 that is -- would not, I think, be considered a 7 formal test. But from the perspective of this 8 biologically plausible mechanism, other 9 scientists undertaking similar methodology came 10 up with similar results. 11 And, so, therefore, I would say that 12 this report is -- continues to be supported by 13 independent reviews and content. 14 MS. BROWN: 15 Q The other scientists that you just 16 referenced are also paid experts for the 17 plaintiffs; is that right? 18 MS. O'DELL: 19 Object to the form. 20 A I don't have knowledge of that 21 specifically. 22 MS. BROWN: 23 Q Well, when you said other experts 24 looking at the same thing came up with a similar</p>	<p>1 for some of this work, but I would counter that 2 with sponsorship of -- of studies that are 3 subsequently peer-reviewed, I think are generally 4 held to a scientific standard and rigor, and 5 would suggest that his most recent work would 6 fall under that and -- and, therefore, I would 7 not consider that in the same realm as an expert 8 report. 9 MS. BROWN: 10 Q Are you aware that the plaintiffs' 11 lawyers funded Dr. Saed's studies? 12 A I am. 13 Q How do you know that? 14 MS. O'DELL: 15 Don't speculate. If you know it, 16 testify to it. 17 A No. I'm thinking of -- 18 That was disclosed during the 19 discussion of the -- of the paper, and the 20 question I asked and actually looked on the paper 21 was to -- 22 And this -- this was getting to my own 23 opinion as to the appropriateness and the 24 potential scientific rigor of the paper, and that</p>

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<p>1 was whether or not Dr. Saed disclosed that</p> <p>2 relationship, which is, of course, ethically a</p> <p>3 requirement for sponsored research. And, indeed,</p> <p>4 that sponsorship is made in the paper.</p> <p>5 MS. BROWN:</p> <p>6 Q Was it important to you --</p> <p>7 Did you ask Dr. Saed about the funding</p> <p>8 for his paper?</p> <p>9 A I did not. As we -- as we discussed, I</p> <p>10 haven't spoken with him.</p> <p>11 Q Were you troubled by the fact that</p> <p>12 Dr. Saed's disclosure does not reference which</p> <p>13 side of the litigation he's working for?</p> <p>14 MS. O'DELL:</p> <p>15 Object to the form.</p> <p>16 A Are you asking for my opinion on if it</p> <p>17 troubled me?</p> <p>18 MS. BROWN:</p> <p>19 Q Yeah.</p> <p>20 A No.</p> <p>21 Q It sounds like you did a little</p> <p>22 investigation and you were satisfied with the</p> <p>23 disclosure. Was that your testimony?</p> <p>24 MS. O'DELL:</p>	<p>1 Q Why is it important, in your mind, to</p> <p>2 disclose funding for a study?</p> <p>3 A Well, it's, you know, ethical premise</p> <p>4 of -- of most scientific research or really all</p> <p>5 extramurally funded research that the funding</p> <p>6 sources are -- are always disclosed. And that's</p> <p>7 true for publication as well as presentation.</p> <p>8 And, so, I think most -- most</p> <p>9 scientists, during presentation, will present a</p> <p>10 slide that shows their -- their funding support</p> <p>11 and all of its sources regard- -- whether it's</p> <p>12 public or private.</p> <p>13 And then you'll notice in vast majority</p> <p>14 of publications, if they are grant supported,</p> <p>15 again, whether that grant is from a public or a</p> <p>16 private institution, those things are referenced.</p> <p>17 And, in fact, the U. S. Government has a</p> <p>18 requirement that grants be referenced in their --</p> <p>19 in any publications that were supported by that</p> <p>20 money.</p> <p>21 Q Do you have any critiques of either of</p> <p>22 Saed's papers?</p> <p>23 A No. Not at this time.</p> <p>24 Q Do you have any questions or anything</p>
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<p>1 Object to the form. He didn't use the</p> <p>2 word "investigation."</p> <p>3 A I was satisfied seeing a disclosure</p> <p>4 made regarding funding, which, again, in the</p> <p>5 scientific climate I would -- or I would state</p> <p>6 simply I viewed the support of that study which</p> <p>7 subsequently goes out to peer review functionally</p> <p>8 equivalent to pharmaceutical support of a study</p> <p>9 involving a drug or a condition or a treatment.</p> <p>10 The reality of the scientific space</p> <p>11 is -- is -- is funding sponsorship comes from a</p> <p>12 variety of cases. And in each institution,</p> <p>13 HudsonAlpha certainly, I'm positive Wayne State</p> <p>14 has a conflict of interest review board which</p> <p>15 Dr. Saed has to report to as far as the -- how he</p> <p>16 manages that potential conflict of interest. And</p> <p>17 given that he's at a reputable institution that</p> <p>18 I've actually done a fair amount of review work</p> <p>19 with over the years, being Wayne State, I'm</p> <p>20 reasonably -- or I would say I'm quite confident</p> <p>21 that his conflict of interest has been managed</p> <p>22 appropriately for the -- for the study that was</p> <p>23 reviewed.</p> <p>24 MS. BROWN:</p>	<p>1 that doesn't make sense to you, having reviewed</p> <p>2 the most recent one or the 2017 one?</p> <p>3 A No. My focus, particularly on the most</p> <p>4 recent one, I actually found his molecular</p> <p>5 studies to be quite comprehensive and --</p> <p>6 So there was -- there was no specific</p> <p>7 concerns that -- that I was able to identify.</p> <p>8 And, again, the -- in the -- in the version of</p> <p>9 the paper that -- that I -- that I was given.</p> <p>10 Q And did you have any opportunity to</p> <p>11 check to see if you had an earlier version of</p> <p>12 that paper?</p> <p>13 A Oh, I -- I'll be sure and do that at</p> <p>14 the next break.</p> <p>15 Q Okay. Why don't we go ahead and take a</p> <p>16 break now. You'll take a look, if you wouldn't</p> <p>17 mind, to see if you have something other than</p> <p>18 what we've marked at the deposition.</p> <p>19 I'm going to renew -- review my notes.</p> <p>20 I'm close to finishing, and then I'll hand it</p> <p>21 over to my colleague, Mr. Ferguson, who I think</p> <p>22 will have some questions for you as well. Okay,</p> <p>23 Doctor?</p> <p>24 A Uh-huh.</p>

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<p style="text-align: right;">Page 302</p> <p>1 Q Thank you, Doctor. 2 VIDEOGRAPHER: 3 Going off the record. The time is 3:33 4 p.m. 5 (OFF THE RECORD.) 6 VIDEOGRAPHER: 7 We're back on the record. The time is 8 3:48 p.m. 9 MS. BROWN: 10 Q Welcome back, Doctor. 11 Did you have an opportunity to take a 12 look if you had an earlier version of Dr. Saed's 13 manuscript? 14 A I did. 15 I did not. 16 Q Okay. And, so, during this deposition, 17 you've referred from time to time to Dr. Saed's 18 2018 paper. Is that right? 19 A (Nods affirmatively.) 20 MS. O'DELL: 21 Object to the form. Excuse me. 22 MS. BROWN: 23 Q And you received that paper after you 24 authored your report in this case; right?</p>	<p style="text-align: right;">Page 304</p> <p>1 MS. BROWN: 2 Q And if that's not the one you were 3 thinking of, Doctor, we can move on. 4 A I was thinking Henderson 1971. 5 Q And that's not an animal study; right? 6 A Maybe this -- this isn't the same one, 7 then. I can certainly find it at the end if -- 8 The -- it was a 1971 study involving a 9 rat model that the major point and conclusion of 10 the study was perhaps something that we've 11 discussed that's been now well accepted that the 12 talc can migrate, after exposure, into the 13 ovarian tissue. 14 Q Are you aware of any study, Doctor, 15 that talc on the exterior of a woman's vagina can 16 migrate up the fallopian tubes to the ovary? 17 MS. O'DELL: 18 Object to the form. 19 A I am not aware of a study that tested 20 that specifically. 21 MS. BROWN: 22 Q And did you consider, in connection 23 with your opinions here, IARC's finding that the 24 science regarding migration is, quote, "weak"?</p>
<p style="text-align: right;">Page 303</p> <p>1 MS. O'DELL: 2 Object to the form. 3 A So I was referring -- 4 Yes. I -- I -- the manuscript we were 5 discussing was received after the completion of 6 this. But, as we discussed earlier, the 7 materials in the paper were presented in abstract 8 form or long abstract form, and those are 9 referenced in the report. 10 MS. BROWN: 11 Q And just to close the loop on one thing 12 before I hand it over to my colleague, 13 Mr. Ferguson, you had referenced an animal study 14 by Woodruff earlier in the day. Do you remember 15 that? 16 A Yes. 17 Q That paper doesn't have anything to do 18 with talc; right? 19 MS. O'DELL: 20 Object to the form. 21 A Let me -- 22 Yes, I -- you're -- the Woodruff 1979 23 paper is not the one I was -- I was wrong on the 24 author. Give me a moment to...</p>	<p style="text-align: right;">Page 305</p> <p>1 MS. O'DELL: 2 Object to the form. 3 A My -- my primary consideration of IARC 4 was their classification of the talc and the -- 5 and the fibrous talc, and I don't recall their 6 conclusions of the migration science being weak. 7 And, in fact, it appears, as stated by 8 the FDA, that the -- the migration question is -- 9 is well resolved. 10 MS. BROWN: 11 Q Finally, Doctor, in connection with 12 your opinions in this case, did you consider 13 articles regarding whether stick lesions evidence 14 inflammation? 15 A I'd have to review some of the 16 literature for stick lesions specifically. But 17 that -- 18 Can you -- what are you referring to by 19 stick lesions? 20 Q So do you understand that it's now 21 believed, in terms of the -- where ovarian cancer 22 begins, that it begins in the fallopian tubes, 23 epithelial ovarian cancer? 24 A I certainly would agree that a -- the</p>

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<p style="text-align: right;">Page 306</p> <p>1 site of initiation, whether -- that it can begin 2 in the fallopian tubes, yes, that there's been 3 studies that have shown that evidence. 4 Q And some of the early lesions that have 5 been found in the fallopian tubes are sometimes 6 referred to as stick lesions. Are you familiar 7 with that? 8 MS. O'DELL: 9 Object to the form. 10 A I'm not. 11 MS. BROWN: 12 So you haven't looked at any studies 13 that have looked at stick lesions that have been 14 removed from women to see if there was any 15 evidence of inflammation? 16 MS. O'DELL: 17 Object to the form. 18 A That -- that -- I don't recall that as 19 part of the review. 20 MS. BROWN: 21 Q Fair enough. 22 No further questions. I'll hand it 23 over to Mr. Ferguson. 24 MR. FERGUSON:</p>	<p style="text-align: right;">Page 308</p> <p>1 the Genomic Services Laboratory -- 2 Right? There's one of those at 3 HudsonAlpha; right? 4 A There is. 5 Q Do you perform services there such as 6 running clinical samples to report results to 7 healthcare providers? Is that the kind of things 8 you do? 9 A To be -- to be clear and to, 10 importantly, differentiate the regulated lab 11 versus the research laboratory, the Genomic 12 Services Laboratory is a -- is a entity of 13 HudsonAlpha that is responsible for research 14 activities. 15 There is a separate wholly owned 16 subsidiary of HudsonAlpha creatively named the 17 Clinical Services Laboratory. So that laboratory 18 is the laboratory that performs the testing. And 19 to hopefully not provide a level of confusion, 20 but the two laboratories coexist in the same 21 space. And what this means is I have staff and 22 equipment. Some is dedicated to clinical, some 23 is dedicated to research, and some are shared 24 between the two.</p>
<p style="text-align: right;">Page 307</p> <p>1 Thank you. 2 EXAMINATION 3 BY MR. FERGUSON: 4 Q Good afternoon, Dr. Levy. My -- my 5 name is Ken Ferguson, and I represent Imerys in 6 this matter. Do you know who Imerys is? 7 A Only that they're a mining company. 8 Q Okay. And I have some questions for 9 you. I apologize for my voice. I've kind of had 10 my allergies and then going into a cold, so it's 11 kind of -- kind of stuffy. So I apologize. 12 If you have trouble hearing me or 13 understanding me, let me know. Okay? 14 A Okay. 15 Q And -- and just -- I know you've been 16 at this with Miss Brown for a little while, but 17 if there's any question that you don't understand 18 that I'm asking you, just let me know, and I'll 19 restate it so I can make sure that we're 20 communicating. Okay? 21 A Okay. 22 Q I want to talk to you, first of all, 23 about a little bit more about what you do at 24 HudsonAlpha Institute. So in the what's called</p>	<p style="text-align: right;">Page 309</p> <p>1 So, in summary, the best way to 2 consider the laboratory is that it's a clinical 3 regulated laboratory that also performs research. 4 Any projects under that research 5 umbrella are referred to as being in the Genomic 6 Services Laboratory. Anything clinical is 7 referred to the Clinical Services Laboratory. 8 That lab has been CLIA-licensed now for going on 9 five -- just past four years and has been 10 CAP-accredited for three and a half. 11 Q So is it the Clinical Services 12 Laboratory, then, that would perform services 13 like running clinical samples to get results to 14 healthcare providers? 15 A That's correct. 16 Q And -- and among those things that the 17 Clinical Services Laboratory does, is that 18 restricted to whole genome sequencing? 19 A Our currently -- the only publicly 20 disclosed and validated test for the Clinical 21 Services Laboratory is whole genome sequencing. 22 We have two other laboratory-developed 23 tests, or commonly referred to as LDTs, that are 24 run in a -- as a private assay for some clinical</p>

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<p style="text-align: right;">Page 310</p> <p>1 trials, so they're not publicly available and to</p> <p>2 date have not been publicly disclosed. They're</p> <p>3 protected under confidentiality agreement.</p> <p>4 And the Clinical Services Laboratory</p> <p>5 this year will launch a number of other tests</p> <p>6 that we have publicly disclosed. Those include</p> <p>7 whole exome sequencing, an oncology panel known</p> <p>8 as the TruSight Tumor 170, which profiles 170</p> <p>9 genes with -- that have been -- that have known</p> <p>10 involvement in cancer risk and progression, and</p> <p>11 as well as a 500 panel of similar form.</p> <p>12 Q So let me talk to you a little bit</p> <p>13 about your prior position. You were at</p> <p>14 Vanderbilt University Medical Center; correct?</p> <p>15 A Correct.</p> <p>16 Q And you were an assistant professor?</p> <p>17 Is that correct?</p> <p>18 A The titles I held there was research</p> <p>19 assistant professor and then assistant professor,</p> <p>20 and then I was a associate professor as an</p> <p>21 adjunct faculty for a number of years after</p> <p>22 joining HudsonAlpha. So I had to progress</p> <p>23 through a few of the academic ranks at</p> <p>24 Vanderbilt, but all of them in the professor</p>	<p style="text-align: right;">Page 312</p> <p>1 of pre-reviews for tenure. There were no</p> <p>2 concerns with that progress. But, based on both</p> <p>3 funding as well as publication records, I wasn't</p> <p>4 overly concerned with that.</p> <p>5 But the opportunity to be able to do --</p> <p>6 and the scale of operations at HudsonAlpha was --</p> <p>7 was too good to turn down, as far as remaining at</p> <p>8 Vanderbilt.</p> <p>9 Q So you were neither granted tenure nor</p> <p>10 denied tenure. Is that fair to say?</p> <p>11 A That's fair to say.</p> <p>12 I think the best evidence for the</p> <p>13 relationship at Vanderbilt after my leaving was I</p> <p>14 continued as an adjunct faculty in the same</p> <p>15 department, again with change in title, for a</p> <p>16 number of years after joining HudsonAlpha. So it</p> <p>17 was a -- certainly, I wouldn't characterize it as</p> <p>18 a negative departure from the institution. And I</p> <p>19 still remain a collaborator with a number of</p> <p>20 colleagues there.</p> <p>21 Q Do you have a copy of your report in</p> <p>22 front of you?</p> <p>23 A I do.</p> <p>24 Q Okay. What I'm gonna do is I'm gonna</p>
<p style="text-align: right;">Page 311</p> <p>1 realm.</p> <p>2 Q As an assistant professor, were you</p> <p>3 appointed on a tenure track?</p> <p>4 A Yes.</p> <p>5 Q And do you know generally how many</p> <p>6 years after appointment as an assistant professor</p> <p>7 is a tenure decision at Vanderbilt typically made</p> <p>8 in that department?</p> <p>9 A It varies from probably five to nine.</p> <p>10 Q Did you ever achieve tenure at</p> <p>11 Vanderbilt?</p> <p>12 A Actually, I was up for tenure the year</p> <p>13 that I moved to HudsonAlpha.</p> <p>14 Q So --</p> <p>15 A So, technically, I, which will sound</p> <p>16 odd, I was promoted to associate professor upon</p> <p>17 leaving.</p> <p>18 Q Okay.</p> <p>19 A In an adjunct role.</p> <p>20 Q So were you turned down for tenure</p> <p>21 or --</p> <p>22 A I was not. I never -- I -- the</p> <p>23 opportunity at HudsonAlpha predated the time that</p> <p>24 I would have gone up for tenure. I had a number</p>	<p style="text-align: right;">Page 313</p> <p>1 try to go through, probably in -- in order,</p> <p>2 portions of your report that I want to ask about</p> <p>3 and try to make sure I don't cover things that</p> <p>4 Miss Brown's already covered.</p> <p>5 Can you look at page 5 of your report?</p> <p>6 A Yes.</p> <p>7 Q So there -- and I'm looking at number 2</p> <p>8 on page 5, Acquired Somatic Gene Mutation.</p> <p>9 Do you see that?</p> <p>10 A I do.</p> <p>11 Q And you say there that --</p> <p>12 I'm skipping the sentences. If you</p> <p>13 need to go back, feel free.</p> <p>14 -- "Biological and lifestyle exposures,</p> <p>15 such as viruses, obesity, hormones and chronic</p> <p>16 inflammation, are also known to result in</p> <p>17 cancer-causing mutations."</p> <p>18 Right?</p> <p>19 A I see that sentence.</p> <p>20 Q Okay. Wouldn't you agree that the</p> <p>21 association between obesity and cancer risk is</p> <p>22 just that, an association and not a known</p> <p>23 cause-and-effect relationship?</p> <p>24 MS. O'DELL:</p>

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<p>1 Object to the form.</p> <p>2 A I would state that it is known that</p> <p>3 cancer rates increase in a number of unhealthy</p> <p>4 conditions, including obesity. But I am not</p> <p>5 aware of a -- of any studies that have</p> <p>6 illustrated a causal effect directly between</p> <p>7 obesity and cancer.</p> <p>8 MR. FERGUSON:</p> <p>9 Q And, specifically, isn't it true that</p> <p>10 there is no direct in vivo experimental evidence</p> <p>11 that obesity causes cancer-causing mutations?</p> <p>12 A I would have to review the literature</p> <p>13 to -- before answering that question. But the</p> <p>14 relationship between obesity and cancer risk</p> <p>15 is -- is quite well established. And I think for</p> <p>16 us to discuss that in more detail, we'd have to</p> <p>17 start delving into some of the specifics around</p> <p>18 the physiological changes related to obesity and</p> <p>19 whether those specific physiological changes play</p> <p>20 a role in cancer.</p> <p>21 Q And, just below that, the last sentence</p> <p>22 in that paragraph, you say, "These mechanisms may</p> <p>23 be direct, such as radiation directly damaging</p> <p>24 DNA, as well as indirect, such as an external</p>	<p>1 A It varies. So the -- the --</p> <p>2 "inflammatory response" is a bit general. So</p> <p>3 depending on specific type of cellular</p> <p>4 recruitment and cellular damage through the</p> <p>5 release of cytokines, the release of oxidative</p> <p>6 damaging materials from cells like granulocytes,</p> <p>7 you know, or the -- even the cell's own</p> <p>8 production of reaction to -- reactive oxygen</p> <p>9 species, such as from the mitochondria, which is</p> <p>10 the most common sync -- or most common source of</p> <p>11 reactive oxygen species in the cell.</p> <p>12 And, so, those are some examples of --</p> <p>13 of that relationship between an inflammatory</p> <p>14 response and that cellular reaction.</p> <p>15 Q Reactive oxygen species are not the</p> <p>16 same thing as inflammation; correct?</p> <p>17 A I would say reactive oxygen species are</p> <p>18 a hallmark of inflammation.</p> <p>19 Q But they're not the same thing.</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form.</p> <p>22 A The -- well, they are --</p> <p>23 Again, reactive oxygen species are a</p> <p>24 component of inflammation. So they're -- the</p>
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<p>1 agent causing a cellular -- cellular reaction or</p> <p>2 inflammatory response that then leads to DNA</p> <p>3 damage or mutation."</p> <p>4 What cellular reactions are you</p> <p>5 referring to that result in DNA damage or</p> <p>6 mutation?</p> <p>7 A So the presence of reactive -- so a few</p> <p>8 different things. Primarily, along the</p> <p>9 discussions for today, the presence of reactive</p> <p>10 oxygen species which can directly -- which are a</p> <p>11 cellular reaction that can then cause -- directly</p> <p>12 cause DNA damage.</p> <p>13 There's protein oxidation effects that</p> <p>14 are similar to that, in the sense that you have a</p> <p>15 chemical change and a cellular component that</p> <p>16 results in a -- in a protein activity change,</p> <p>17 again leading to potential DNA damage.</p> <p>18 And then you can have --</p> <p>19 So those are two -- two examples of</p> <p>20 cellular reactions to that.</p> <p>21 Q And -- and maybe you just explained it,</p> <p>22 but I wanted to make sure I'm clear. What is the</p> <p>23 mechanism by which an inflammatory response</p> <p>24 results in DNA damage?</p>	<p>1 words are two -- two different definitions, but</p> <p>2 they are a component.</p> <p>3 MR. FERGUSON:</p> <p>4 Q Would you agree that reactive oxygen</p> <p>5 species are a normal part of cell physiology?</p> <p>6 A Yes, absolutely.</p> <p>7 Q And the major source of reactive oxygen</p> <p>8 species comes from inside the cell and is</p> <p>9 produced in mitochondria?</p> <p>10 A A source, and depending on the site of</p> <p>11 the physiology. So a normal, healthy cell not</p> <p>12 under stress or injury would be -- then, yes,</p> <p>13 that's a true statement.</p> <p>14 Under different physiological</p> <p>15 conditions, that statement may not be true.</p> <p>16 Q Can you distinguish reactive oxygen</p> <p>17 species produced inside a cell from reactive</p> <p>18 oxygen species produced outside the cell?</p> <p>19 A What do you mean? So by -- by</p> <p>20 "distinguish," you mean --</p> <p>21 Q Can you tell the difference?</p> <p>22 A I'm just thinking if there's a way to</p> <p>23 measure.</p> <p>24 So you can measure the effects of</p>

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<p style="text-align: right;">Page 318</p> <p>1 exogenously introduced reactive oxygen species 2 and then compare that to the measurement of 3 endogenously produced reactive oxygen species. 4 But as far as determining the 5 difference if the cellular integrity is not 6 intact, I'm not aware of a method to do that. 7 Q Would you agree that generation of 8 reactive oxygen species is an inevitable 9 consequence of aging in aerobic organisms? 10 MS. O'DELL: 11 Object to the form. 12 A So reactive oxygen species are a -- 13 are present at all stages of life. And aging, as 14 a biological phenomenon, is probably one of the 15 most variable phenomenon that exists. 16 And specific to reactive oxygen 17 species, the diet, lifestyle, and genetics of 18 that individual will drastically change that. 19 And a new area of research that my 20 laboratory has been undertaking for a short 21 time -- 22 And, so, I don't have specific 23 publications, and it's really not -- I promise 24 it's not taking us too far afield.</p>	<p style="text-align: right;">Page 320</p> <p>1 would be very difficult. 2 MR. FERGUSON: 3 Q In your report, on this same page, you 4 discuss the fact that, even if someone has a 5 genetic mutation that predisposes them to cancer 6 doesn't mean that he or she is certain to get 7 cancer. Correct? 8 A That is correct. 9 Q So there is a -- a random component to 10 the effects of known cancer-causing agents. 11 Right? 12 MS. O'DELL: 13 Objection to form. 14 A There is a complicated relationship 15 between genetics, environment, and expose -- or 16 environment, including exposure and lifestyle, 17 and the progression of cancer. 18 Perhaps the -- a summary analogy is the 19 more predisposing mutations that an individual 20 has, it's -- it's equivalent to their body is 21 rolling the dice more often to collect a mutation 22 sufficient to cause cancer than somebody who does 23 not have the same genetic background. 24 And there's -- there's many, many lines</p>
<p style="text-align: right;">Page 319</p> <p>1 -- but is the concept of your annual 2 age versus biological age. And my lab has some 3 assays that are based on epigenetics as well as 4 some metabolomic markers. And what we found -- 5 now, in very, again, preliminary data -- that 6 individuals will vary by plus or minus 15 years 7 from physiological age to annual age based on, 8 again, a number of lifestyle factors not 9 important for this study. 10 But the point I'm making is the 11 discussion about level of reactive oxygen species 12 and its association with age is actually quite 13 variable based on the long -- or based on the 14 current physiological activity of that person. 15 Stated very simply, which is probably 16 something we all know, the better shape you're 17 in, the younger your physiology will appear. And 18 you can actually modulate that quite quickly, 19 meaning that a person who's 60 and has made poor 20 lifestyle choices can actually gain back quite a 21 bit of that physiological age quite quickly. 22 And so, again, to directly answer your 23 question, a annual age-related conclusion 24 regarding production of reactive oxygen species</p>	<p style="text-align: right;">Page 321</p> <p>1 of evidence. Probably the most prominent is 2 BRCA1 and 2 mutation and the role it plays in 3 increased risk of breast and ovarian cancer. 4 MR. FERGUSON: 5 Q Wouldn't you agree that even the 6 inherited susceptibility cannot entirely explain 7 this random component of some people getting 8 cancer when exposed and some people not? 9 MS. O'DELL: 10 Objection to form. 11 A DNA -- so that, it's very 12 gene-dependent. So BRCA1 and 2 is the example 13 given. That is correct, that if you have a BRCA1 14 and -- 1 or 2 mutation, you are not guaranteed to 15 get cancer. 16 Corollary to that is if you do not have 17 a BRCA1 and 2 mutation, your relative risk for 18 cancer does not change, meaning that you're at no 19 less of a risk than somebody -- somebody else who 20 doesn't have that mutation. 21 I should state that there are other 22 genes. P53 is a good example that was mentioned 23 earlier. If you carry a mutation in that gene, 24 the probability that you'll get cancer, assuming</p>

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<p>1 you don't die from something else, is almost</p> <p>2 certain, meaning that it's in the mid to high 90</p> <p>3 percents if you -- if you live until a late age.</p> <p>4 MR. FERGUSON:</p> <p>5 Q Further down this paragraph, you</p> <p>6 indicate that "An inherited gene mutation could</p> <p>7 instead make one more likely to develop cancer</p> <p>8 when exposed to certain cancer-causing</p> <p>9 substances."</p> <p>10 Correct? That's your statement?</p> <p>11 A Yes.</p> <p>12 Q Can you provide any examples in which a</p> <p>13 woman with an inherited mutation in a particular</p> <p>14 gene has been demonstrated to have more</p> <p>15 sensitivity to developing ovarian cancer as a</p> <p>16 result of exposure to an environmental agent?</p> <p>17 A Not for ovarian cancer specifically. I</p> <p>18 would need to review --</p> <p>19 There is a -- I've seen report of a</p> <p>20 single gene related to ovarian cancer, which,</p> <p>21 again, I would have to do a bit of searching to</p> <p>22 be sure I'm naming the correct gene, but I --</p> <p>23 where that has a much high- -- increased risk</p> <p>24 specific to ovarian cancer, but I do not recall</p>	<p>1 And the point of my mentioning this is</p> <p>2 to illustrate that an early predisposition to --</p> <p>3 or a significant predisposition to cancer that</p> <p>4 results in a early cancer event, those</p> <p>5 individuals show a lifetime increase in risk of</p> <p>6 approximately -- they're -- they're approximately</p> <p>7 six times, depending on the disease, to 13 times</p> <p>8 more likely to get that -- to get a secondary</p> <p>9 disease.</p> <p>10 So there clearly is a relationship to</p> <p>11 predisposition in -- in oncology -- or in rate of</p> <p>12 cancer event.</p> <p>13 Q Okay. And I appreciate your response.</p> <p>14 But remember that my question was related to</p> <p>15 ovarian cancer, and -- and we went a little</p> <p>16 afield from ovarian cancer.</p> <p>17 And I want to ask you another question</p> <p>18 in that regard. Can you provide any example in</p> <p>19 which a woman with an inherited mutation in a</p> <p>20 particular gene has been demonstrated to have</p> <p>21 more sensitivity to developing ovarian cancer as</p> <p>22 a result of exposure to talcum powder?</p> <p>23 MS. O'DELL:</p> <p>24 Object to the form.</p>
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<p>1 if there was a measurement of any exogenous</p> <p>2 exposure risk that amplified that effect or not.</p> <p>3 But I think the -- as a general</p> <p>4 premise, it is a -- well established in cancer</p> <p>5 biology that any mu- -- any mutation that results</p> <p>6 in a burden related to DNA repair, related to</p> <p>7 cell cycle control, you are more susceptible to</p> <p>8 cancer.</p> <p>9 In one of our lines of research where</p> <p>10 we do have some publications, in pediatric</p> <p>11 cancer, I would simply point to in approximately</p> <p>12 50 percent of adults who are survivors of</p> <p>13 childhood cancer will develop a second cancer</p> <p>14 event primarily because their -- the fact that</p> <p>15 they developed a childhood cancer generally means</p> <p>16 you are predisposed to that condition.</p> <p>17 And -- and, as evidenced in the</p> <p>18 observations we've done in the analysis of</p> <p>19 thousands of patients in collaboration with</p> <p>20 St. Jude and the children's oncology group, we've</p> <p>21 identified now a ability to do genetic counseling</p> <p>22 in those individuals and predict with very high</p> <p>23 accuracy what their secondary cancer is likely to</p> <p>24 be.</p>	<p>1 Answer the question.</p> <p>2 A So the mechanism we proposed would be</p> <p>3 independent of -- of that predisposition. But I</p> <p>4 would have the opinion that an individual with</p> <p>5 any predisposition mutation, regardless of the</p> <p>6 gene but -- and -- in ovarian cancer, that they</p> <p>7 would be a more fragile individual as -- when it</p> <p>8 comes to this exposure under the mechanism that</p> <p>9 we've been discussing today.</p> <p>10 MR. FERGUSON:</p> <p>11 Q Okay. And what I'm looking for is some</p> <p>12 example or some literature in that regard.</p> <p>13 A I would -- I would have to -- I would</p> <p>14 have to look --</p> <p>15 Q Okay.</p> <p>16 A -- to see.</p> <p>17 Q So what you've told me is that's your</p> <p>18 opinion, but you don't have any references for it</p> <p>19 as you sit here?</p> <p>20 MS. O'DELL:</p> <p>21 Objection to form.</p> <p>22 A So my -- what was -- I was requested to</p> <p>23 provide this biologically plausible mechanism,</p> <p>24 and part of that request was not necessarily</p>

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<p style="text-align: right;">Page 326</p> <p>1 include the influence on that mechanism that</p> <p>2 specific gene mutations or inherited risks may</p> <p>3 have within relation to ovarian cancer.</p> <p>4 So I'd certainly be delighted to pause</p> <p>5 for a moment and take -- you know, and -- and</p> <p>6 work on that -- give you that -- see if I can</p> <p>7 give you that specific example.</p> <p>8 MR. FERGUSON:</p> <p>9 Q But you can't as you sit here?</p> <p>10 A I cannot.</p> <p>11 Q Okay. So let's look at -- further down</p> <p>12 on page 5, you have a section entitled "The Role</p> <p>13 of Genetics in Ovarian Cancer." Correct?</p> <p>14 A Correct.</p> <p>15 Q And I want to look at a reference that</p> <p>16 you -- you have cited. And let me mark this as</p> <p>17 an exhibit, please. I guess I can mark it.</p> <p>18 (DEPOSITION EXHIBIT NUMBER 21</p> <p>19 WAS MARKED FOR IDENTIFICATION.)</p> <p>20 MR. FERGUSON:</p> <p>21 Q Exhibit 21 is the Nunes article. Have</p> <p>22 you seen that?</p> <p>23 A I have, yes.</p> <p>24 Q Okay. So if we look at page 5, at top</p>	<p style="text-align: right;">Page 328</p> <p>1 further and you have a sentence that starts</p> <p>2 "epithelial ovarian cancer." Correct?</p> <p>3 MS. O'DELL:</p> <p>4 On page 6 there?</p> <p>5 MR. FERGUSON:</p> <p>6 Yeah. I apologize. Yeah, it is.</p> <p>7 A Yep.</p> <p>8 MR. FERGUSON:</p> <p>9 Q It's on page 6. It's the, I believe,</p> <p>10 the last sentence of the partial paragraph at the</p> <p>11 top of 6. See it?</p> <p>12 A I do.</p> <p>13 Q Okay. And you say, "Epithelial ovarian</p> <p>14 cancer (EOC) includes most malignant ovarian</p> <p>15 neoplasms" -- you cite Chan, 2006 -- "that can be</p> <p>16 classified based on morphologic and molecular</p> <p>17 genetic features into the following types:</p> <p>18 Serous" -- and, in parentheses, "(OSC) low and</p> <p>19 high grade); endometrioid (EC), clear cell,</p> <p>20 (OCCC), and mucinous (MC) carcinomas."</p> <p>21 Correct?</p> <p>22 A Correct.</p> <p>23 Q Okay. And then if we look back at page</p> <p>24 2 of Nunes, in the second sentence of the first</p>
<p style="text-align: right;">Page 327</p> <p>1 of the page, you indicate that ovarian cancer is</p> <p>2 the major cause of death from gynecologic disease</p> <p>3 and the second most common gynecologic malignancy</p> <p>4 worldwide; correct?</p> <p>5 A Correct.</p> <p>6 Q And then in your report you cite Nunes</p> <p>7 and Serpa, the article we've just marked as</p> <p>8 Exhibit 21, as well as Siegel and Torre; correct?</p> <p>9 A Yes.</p> <p>10 Q If we look at page 2 of the Nunes</p> <p>11 article, the exact same sentence appears on -- at</p> <p>12 the bottom of page 2 under the heading of</p> <p>13 "Ovarian Cancer, an Overview"; correct?</p> <p>14 A Correct.</p> <p>15 Q Right.</p> <p>16 A That's correct.</p> <p>17 Q Okay. And it's --</p> <p>18 A It's not quite the same sentence, given</p> <p>19 that it's the same initial statement, not an</p> <p>20 identical sentence.</p> <p>21 Q Very close to identical?</p> <p>22 A Well, they -- they both -- they both</p> <p>23 introduce the same facts.</p> <p>24 Q Okay. Then if we go down a little bit</p>	<p style="text-align: right;">Page 329</p> <p>1 paragraph under "Ovarian Cancer, an Overview,"</p> <p>2 the nearly identical sentence appears there.</p> <p>3 Correct?</p> <p>4 MS. O'DELL:</p> <p>5 Object to the form.</p> <p>6 A The two sentences stating the same</p> <p>7 fundamental facts regarding ovarian cancer and</p> <p>8 the histological types are -- yes, I agree.</p> <p>9 MR. FERGUSON:</p> <p>10 Q With almost the same wording.</p> <p>11 MS. O'DELL:</p> <p>12 Object to the form.</p> <p>13 A They have similar wording.</p> <p>14 MR. FERGUSON:</p> <p>15 Q Remarkably similar; correct?</p> <p>16 MS. O'DELL:</p> <p>17 Object to the form.</p> <p>18 A I wouldn't call it -- so they --</p> <p>19 Again, we're stating fundamental basic</p> <p>20 facts around histological type and following a</p> <p>21 number of, again, factual observations for what</p> <p>22 the state of the art for genetic knowledge</p> <p>23 in -- in different genes and different proteins</p> <p>24 is as it relates to our understanding of -- of</p>

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<p style="text-align: right;">Page 330</p> <p>1 cancer with, again, appropriate reference for</p> <p>2 those -- for those studies.</p> <p>3 MR. FERGUSON:</p> <p>4 Q And then if we look at the following</p> <p>5 paragraphs, the first full paragraph there on</p> <p>6 page 6, in your report you have a sentence that</p> <p>7 starts "low grade OSC cases generally have</p> <p>8 genetic alterations" in a number of items you've</p> <p>9 listed; correct?</p> <p>10 A Correct.</p> <p>11 Q Okay. And that sentence ends with the</p> <p>12 words or "p13/Ras/Notch/FOXMI." Correct?</p> <p>13 A Correct.</p> <p>14 Q Okay. And then if we go back to Nunes,</p> <p>15 if you look at that same paragraph we've been</p> <p>16 talking about -- and those -- there's an</p> <p>17 introductory phrase that you don't have, and then</p> <p>18 it starts with "low grade OSC generally</p> <p>19 comprising." Slightly different wording, but you</p> <p>20 list the same types of receptors and the same</p> <p>21 types of items. Correct?</p> <p>22 A Yes. That's providing a review of,</p> <p>23 again, the known associations between specific</p> <p>24 ovarian subtypes and their most commonly referred</p>	<p style="text-align: right;">Page 332</p> <p>1 MS. O'DELL:</p> <p>2 I'm sorry.</p> <p>3 MR. FERGUSON:</p> <p>4 Q -- on page 2.</p> <p>5 A Yes.</p> <p>6 MR. FERGUSON:</p> <p>7 Sorry. Leigh, it's on page -- the</p> <p>8 bottom of page 2.</p> <p>9 MS. O'DELL:</p> <p>10 Oh, I'm there. When you said the top,</p> <p>11 I got --</p> <p>12 MR. FERGUSON:</p> <p>13 No worries. That's -- my mistake.</p> <p>14 Q Okay. It says "EC subtypes," and then</p> <p>15 it goes to mucin-coding genes on the top of page</p> <p>16 3. Correct?</p> <p>17 A Correct.</p> <p>18 Q Again, that paragraph is nearly</p> <p>19 identical to the one in your report. Correct?</p> <p>20 MS. O'DELL:</p> <p>21 Object to the form.</p> <p>22 MR. FERGUSON:</p> <p>23 Q Same word, same order, same citations;</p> <p>24 correct?</p>
<p style="text-align: right;">Page 331</p> <p>1 genetic information or genetic predis- --</p> <p>2 sorry -- mutated genes. So I'm -- that's right.</p> <p>3 Q Okay.</p> <p>4 A They are -- they are similar in that</p> <p>5 both are, again, introducing factual information</p> <p>6 about the current knowledge in ovarian cancer in</p> <p>7 this literature, again pointing out that</p> <p>8 referencing the papers that they both came from,</p> <p>9 being the Nunes as well as the appropriate</p> <p>10 references.</p> <p>11 Q Okay. And, then, the paragraph below</p> <p>12 that starts endo- -- "endometrioid carcinoma,"</p> <p>13 paren, "(EC)." Correct?</p> <p>14 A Correct.</p> <p>15 Q If we look --</p> <p>16 And then that goes all the way to the</p> <p>17 word "mucin-coding genes" with two citations;</p> <p>18 correct?</p> <p>19 A Correct.</p> <p>20 Q If we look at 2 and the top of page 3</p> <p>21 in Nunes, there's a sentence that starts "EC."</p> <p>22 It does not spell out endometrioid carcinoma. Do</p> <p>23 you see that four lines from the top? I'm sorry.</p> <p>24 Four lines from the bottom --</p>	<p style="text-align: right;">Page 333</p> <p>1 MS. O'DELL:</p> <p>2 Object to the form.</p> <p>3 A So my -- my report is similar to the</p> <p>4 review article. It -- it's listing the subtypes</p> <p>5 of ovarian cancer and -- based on the Nunes</p> <p>6 paper, which is a 2018 publication, so a more</p> <p>7 current review. I'm, again, providing that</p> <p>8 referenced information about the -- the -- this</p> <p>9 observation.</p> <p>10 Q You're citing the same references as</p> <p>11 Nunes; correct?</p> <p>12 A Yes.</p> <p>13 Q You cite the -- the various gene --</p> <p>14 expression of gene in the same order they do,</p> <p>15 so --</p> <p>16 Correct?</p> <p>17 A Yes.</p> <p>18 Q And is that just coincidental? That's</p> <p>19 just happened? You happened to have put this</p> <p>20 paragraph in the same order with the same</p> <p>21 notations as -- as Nunes?</p> <p>22 MS. O'DELL:</p> <p>23 Object to the form.</p> <p>24 A Well, I'm listing the same information</p>

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<p style="text-align: right;">Page 334</p> <p>1 that's contained in the Nunes paper. And seeing</p> <p>2 as that -- this was a review of the literature</p> <p>3 with -- you know, based on the state of the art,</p> <p>4 the Nunes review is exactly that. And, again,</p> <p>5 I'm -- I'm repeating the information regarding</p> <p>6 the specific gene information as it relates to</p> <p>7 this -- this ovarian cancer risk and -- and --</p> <p>8 and, again, appropriately citing the basic</p> <p>9 studies as Nunes did.</p> <p>10 MR. FERGUSON:</p> <p>11 Q With virtually the same wording?</p> <p>12 A With similar wording, yes.</p> <p>13 Q Let's look at page -- page 7.</p> <p>14 MS. O'DELL:</p> <p>15 His report?</p> <p>16 MR. FERGUSON:</p> <p>17 Q Yeah. I apologize. Your report.</p> <p>18 We can set Nunes aside now.</p> <p>19 You have a paragraph starts -- that</p> <p>20 starts "individuals can inherit mutations in</p> <p>21 BRCA1, BRCA2 or p53."</p> <p>22 See it?</p> <p>23 A Uh-huh.</p> <p>24 Q And you say, "These defects allow</p>	<p style="text-align: right;">Page 336</p> <p>1 or p53 mutations can be considered causes of</p> <p>2 cancer?</p> <p>3 MS. O'DELL:</p> <p>4 Object to the form.</p> <p>5 A No. Not -- not specifically causal. I</p> <p>6 think the -- each of these -- as we've discussed,</p> <p>7 each of these genes, BRCA1 and BRCA2, or starting</p> <p>8 with BRCA1 and BRCA2, increase the probability of</p> <p>9 a -- of a person -- generally women -- getting</p> <p>10 breast or ovarian cancer but do not exclusively</p> <p>11 mean somebody with that mutation will get cancer.</p> <p>12 So, with that knowledge, I would not</p> <p>13 consider BRCA1 and BRCA2 mutation alone</p> <p>14 sufficient to cause cancer. It increased the</p> <p>15 risk.</p> <p>16 And, as we talked about, p53 is a bit</p> <p>17 more of a higher-risk gene, and the question as</p> <p>18 to whether or not it is possible for someone to</p> <p>19 have a -- what the rate of someone having a p53</p> <p>20 mutation and not getting cancer, I believe, is</p> <p>21 currently unknown. But there, again, is a much</p> <p>22 higher probability of developing -- developing</p> <p>23 cancer.</p> <p>24 MR. FERGUSON:</p>
<p style="text-align: right;">Page 335</p> <p>1 additional mutations to accumulate in cells and</p> <p>2 lead to a higher probability of cells being</p> <p>3 cancerous."</p> <p>4 Correct?</p> <p>5 A Correct.</p> <p>6 Q And you've indicated earlier in your</p> <p>7 report that cancer is caused by mutations.</p> <p>8 Correct?</p> <p>9 A Correct.</p> <p>10 Q And you say here that mutations in</p> <p>11 BRCA1, BRCA2 or p53 can result in the</p> <p>12 accumulation of additional mutations in cells.</p> <p>13 Correct?</p> <p>14 MS. O'DELL:</p> <p>15 Object to the form.</p> <p>16 A Yeah. I made the statement that BRCA1,</p> <p>17 BRCA2 and p53, they can be inherited and then, in</p> <p>18 turn, positive for those gene mutations.</p> <p>19 MR. FERGUSON:</p> <p>20 Q Okay. Would you --</p> <p>21 A So I guess if you could ask the</p> <p>22 question again to make sure I understand it.</p> <p>23 Q Well, let me -- doesn't this paragraph</p> <p>24 mean, in your comments here, that BRCA1, BRCA2,</p>	<p style="text-align: right;">Page 337</p> <p>1 Q And then the last line there of page 7,</p> <p>2 you say, "The lifetime risk for ovarian cancer is</p> <p>3 approximately 40 percent for BRCA1 carriers and</p> <p>4 15 to 20 percent for BRCA2 carriers."</p> <p>5 Correct?</p> <p>6 A Correct. Based on -- based on the</p> <p>7 study that I referenced, yes.</p> <p>8 Q Right.</p> <p>9 And -- and the -- the -- if we look at</p> <p>10 the increased risk of 40 percent as compared to</p> <p>11 the risk of cancer in the -- of ovarian cancer in</p> <p>12 the general population, that's a 25-fold increase</p> <p>13 for BRCA1 and about a 7- or 8-fold increase for</p> <p>14 BRCA2; correct?</p> <p>15 MS. O'DELL:</p> <p>16 Object to the form.</p> <p>17 A I -- I would have to -- to determine</p> <p>18 that. But I would say so. I'm certainly</p> <p>19 comfortable stating that the lifetime risk for</p> <p>20 ovarian cancer is approximately 40 percent. I'd</p> <p>21 have to verify your -- your math about that</p> <p>22 indicating a 25-fold increase.</p> <p>23 MR. FERGUSON:</p> <p>24 Q Do you know what the rate in the</p>

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<p style="text-align: right;">Page 338</p> <p>1 general population of ovarian cancer is?</p> <p>2 A It's fairly low. If I -- thinking of</p> <p>3 the cohort studies that were reviewed as part of</p> <p>4 this, it was roughly a hundred to 200 cases per</p> <p>5 30- to 40,000 women in those -- in those studies,</p> <p>6 so relatively low.</p> <p>7 Q And if we go to the top of the next</p> <p>8 page, you say -- it's page 8 -- "Therefore, the</p> <p>9 presence of mutations in the BRCA genes do not</p> <p>10 guarantee that carriers will get cancer. The</p> <p>11 presence of these mutations increases a person's</p> <p>12 risk of developing cancer when exposed to a</p> <p>13 carcinogen."</p> <p>14 Correct?</p> <p>15 A Correct.</p> <p>16 Q And you cite Park, Vitonis, and Wu for</p> <p>17 that. Is that correct?</p> <p>18 A That's correct.</p> <p>19 Q Looking at Park, isn't it true that</p> <p>20 Park does not supply any evidence to support your</p> <p>21 claim that mutations in BRCA1, BRCA2 and/or p53</p> <p>22 increase a person's risk of developing cancer</p> <p>23 when exposed to a carcinogen?</p> <p>24 A I'd have to remind myself of what's in</p>	<p style="text-align: right;">Page 340</p> <p>1 So the -- the Park paper does discuss</p> <p>2 the relationship of ovarian cancer risk relative</p> <p>3 to benign gynecological conditions.</p> <p>4 Q And -- and your comment that you've</p> <p>5 cited these studies for is the presence of these</p> <p>6 mutations increases a person's risk of developing</p> <p>7 cancer when exposed to a carcinogen. And these</p> <p>8 mutations would be what you've been talking about</p> <p>9 in this paragraph, the B -- the BRCA1, BRCA2, and</p> <p>10 p53; correct?</p> <p>11 MS. O'DELL:</p> <p>12 Object to the form.</p> <p>13 A The sentence is worded, "The presence</p> <p>14 of these mutations increases a person's risk of</p> <p>15 developing cancer when exposed to a carcinogen."</p> <p>16 MR. FERGUSON:</p> <p>17 Q Right. Right.</p> <p>18 And, for example, in Vitonis, isn't it</p> <p>19 true that BRCA1, BRCA2 and p53 were not even</p> <p>20 determined in that study and, instead, Jewish</p> <p>21 ethnicity was used as a surrogate for a woman's</p> <p>22 risk of having a mutation in one of these genes?</p> <p>23 Do you recall that --</p> <p>24 A Again, I would have --</p>
<p style="text-align: right;">Page 339</p> <p>1 Park.</p> <p>2 Q Are you going through the entirety of</p> <p>3 the article?</p> <p>4 A I'm just reminding myself the content</p> <p>5 to see if I could find something that was</p> <p>6 specifically related to your question about the</p> <p>7 presence of a BRCA1 or 2 mutation.</p> <p>8 Q Okay. Is the BRCA1, BRCA2, p53, any of</p> <p>9 those even mentioned in the article?</p> <p>10 And -- and I'm not sure we'll have time</p> <p>11 for you to go through each one of them in this</p> <p>12 much --</p> <p>13 You've got -- you cited them for these</p> <p>14 propositions. I'm trying to ask you why you</p> <p>15 cited them for this proposition.</p> <p>16 A I -- I'd have to look in more detail.</p> <p>17 I don't have a specific answer regarding the --</p> <p>18 regarding BRCA1 --</p> <p>19 Q Okay.</p> <p>20 A -- I'm sorry -- BRCA genes.</p> <p>21 I would suspect the Park reference was</p> <p>22 more in the discussion of overall relative risk</p> <p>23 of developing cancer and not necessarily</p> <p>24 exclusive to the presence of a mutation.</p>	<p style="text-align: right;">Page 341</p> <p>1 Q -- one way or the other?</p> <p>2 MS. O'DELL:</p> <p>3 Objection.</p> <p>4 A I would have to review the -- review</p> <p>5 the paper. Because part of the review is to</p> <p>6 be -- include appropriate references with regards</p> <p>7 to ovarian cancer risk, and those may -- I think</p> <p>8 those publications provide some information in</p> <p>9 that space.</p> <p>10 MR. FERGUSON:</p> <p>11 Q All right. But when you cite studies</p> <p>12 for a statement in your report, shouldn't the</p> <p>13 studies relate to that statement?</p> <p>14 MS. O'DELL:</p> <p>15 Object to the form.</p> <p>16 A Well, the studies relate to a person's</p> <p>17 risk of developing cancer. But I -- I think</p> <p>18 it -- it doesn't change the accuracy of the</p> <p>19 presence of the mutation relative to that risk.</p> <p>20 But the -- I don't have a -- a good answer as far</p> <p>21 as relationship of BRCA1 and 2 to the Park paper.</p> <p>22 MR. FERGUSON:</p> <p>23 Q And -- and, then --</p> <p>24 Well, we talked about Vitonis, too.</p>

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<p style="text-align: right;">Page 342</p> <p>1 And then let's get to Wu. 2 MS. O'DELL: 3 Object to the form. You didn't comment 4 specifically about Vitonis, if you've got an 5 issue with Vitonis. You know, it's not fair to 6 assume that because I don't think you asked a 7 direct question. 8 MR. FERGUSON: 9 Okay. I thought I did, but I could be 10 mistaken. 11 MS. O'DELL: 12 You mentioned it, but I don't think 13 you -- I think it was more you rather than asking 14 a question. 15 MR. FERGUSON: 16 Q With regard to Wu, do you recall that, 17 in Wu, BRCA1, BRCA2, and p53 inherited carrier 18 mutation status were not even determined in that 19 study? Do you recall that -- 20 A The -- 21 Q -- one way or the other? 22 MS. O'DELL: 23 Object to the form. 24 A The Wu paper specifically discussed</p>	<p style="text-align: right;">Page 344</p> <p>1 syndrome patients have an increased risk of 2 cancer when exposed to a carcinogen. Correct? 3 A Correct. 4 Q What carcinogens are you referring to? 5 A I'm not -- not referring to a specific 6 carcinogen. I'm using the term "carcinogen" to 7 refer to an insult that would result in DNA 8 damage specifically because, similar to the BRCA 9 mutations, Lynch syndrome impairs DNA mismatch 10 repair. 11 So that defect alone is not sufficient 12 to result in a cellular transformation, so 13 something else has to occur. And when we 14 consider that carcinogens are -- the term 15 "carcinogen" generally refers to something that 16 has the potential to damage cellular components 17 or DNA, it's putting the -- 18 Inability to repair along with the 19 presence of a carcinogen is where that sentence 20 comes from. 21 Q So -- and I want to make sure I 22 understand what you're saying. Are you saying 23 that Lynch syndrome patients have an increased 24 risk of developing cancer after exposure to a</p>
<p style="text-align: right;">Page 343</p> <p>1 nongenetic risk factors. 2 MR. FERGUSON: 3 Q Let's go to the next paragraph, and 4 there you talk about single nucleotide variance, 5 SNVs; correct? 6 A Towards the bottom of the paragraph. 7 As -- in terms of modifiers, yes. 8 Q Yeah. Are -- are single nucleotide 9 variants mutations? 10 A Yes. 11 Q Do most SNVs result in functionally 12 defective proteins? 13 A Statistically speaking on a genome-wide 14 basis, no. 15 So a -- a single nucleotide variant is 16 a variant at any point. And if we consider 17 statistically that about 1 percent of the genome 18 encodes proteins, again, it's statistically less 19 likely that any SNV would affect a protein. 20 Q Okay. Let's look at the next 21 paragraph. There you talk about Lynch syndrome; 22 correct? 23 A Correct. 24 Q And you make a statement that Lynch</p>	<p style="text-align: right;">Page 345</p> <p>1 carcinogen, just like everyone else? 2 A No. I'm stating that Lynch syndrome -- 3 MS. O'DELL: 4 Object to the form. Excuse me. 5 A Lynch syndrome is a hereditary 6 condition that increases the overall risk of 7 cancer to an individual, similar to BRCA1 and 2 8 mutation. 9 MR. FERGUSON: 10 Q So you -- are you claiming that Lynch 11 syndrome patients have a greater increase in 12 relative risk when exposed to a particular 13 carcinogen than do people without Lynch syndrome? 14 MS. O'DELL: 15 Object to the form. 16 A No, I'm not making that statement, to a 17 specific carcinogen. 18 MR. FERGUSON: 19 Q In your next paragraph you talk of -- 20 you start with "Myriad Genetics," and you say, 21 "As with all inherited traits, a positive family 22 history is the strongest indicator of the 23 presence of genetic risk alleles in an 24 individual."</p>

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<p style="text-align: right;">Page 346</p> <p>1 Correct?</p> <p>2 A Correct.</p> <p>3 Q Isn't it true that many women who have</p> <p>4 inherited mutations like BRCA1 or BRCA2 and genes</p> <p>5 that predispose to ovarian cancer development do</p> <p>6 not have a family history of breast or ovarian</p> <p>7 cancer?</p> <p>8 A So the -- your -- your question is a</p> <p>9 little bit different than the statement. So</p> <p>10 the -- if I could clarify the statement in the</p> <p>11 report, it is more that a positive family history</p> <p>12 would be a likely indicator that someone has a</p> <p>13 genetic risk variant such as BRCA1 and 2.</p> <p>14 Q Isn't it true that family history is</p> <p>15 not a sensitive or specific indicator of</p> <p>16 whether -- of whether a particular woman has</p> <p>17 inherited a mutation in a gene associated with</p> <p>18 increased risk of ovarian cancer?</p> <p>19 MS. O'DELL:</p> <p>20 Object to the form.</p> <p>21 A I would say that family -- I would ask</p> <p>22 to define "sensitive" or "specific," because in</p> <p>23 genetics overall, family history remains a</p> <p>24 valuable and important characteristic in terms of</p>	<p style="text-align: right;">Page 348</p> <p>1 number higher than that if you're looking at</p> <p>2 indirect or genetic complex formation.</p> <p>3 You know, depends how far down the</p> <p>4 cellular control and signal transduction and</p> <p>5 growth and proliferation road that we go as far</p> <p>6 as how many genes. But I'm sure, as everyone</p> <p>7 well appreciates, everything in biology is</p> <p>8 interrelated in some form.</p> <p>9 And, so, it -- but I would say this</p> <p>10 statement here is that our ability to look at</p> <p>11 large-scale genetic analysis in individuals of a</p> <p>12 variety of cancer types, given the number of</p> <p>13 individuals affected by cancer and the analysis</p> <p>14 of their genetics, we've been able to identify</p> <p>15 many of -- many of the fundamental or most --</p> <p>16 perhaps most of the fundamental genes involved in</p> <p>17 that initial disease initiation or progression.</p> <p>18 It's important that it is not a</p> <p>19 comprehensive list. Hence, it is not "all," but</p> <p>20 there are a large number of genes that are well</p> <p>21 established.</p> <p>22 Q Okay. Let's look at the next page, 10.</p> <p>23 And you have a paragraph that starts</p> <p>24 "Macrophages."</p>
<p style="text-align: right;">Page 347</p> <p>1 determining the genetic component of -- of any</p> <p>2 disease, cancer included. And, so, if there's</p> <p>3 something exact regarding its sensitivity or</p> <p>4 specificity that I can comment on, I will if I</p> <p>5 know the answer. But...</p> <p>6 MR. FERGUSON:</p> <p>7 Q In -- in the top of the page -- of</p> <p>8 page 9, the next page, you indicate, "Because of</p> <p>9 the large number of individuals tested and the</p> <p>10 ability to trace their genetic inheritance, the</p> <p>11 genes involved in cancer development are well</p> <p>12 established."</p> <p>13 Is that correct?</p> <p>14 A Correct. That's what I state. I did</p> <p>15 make that statement.</p> <p>16 Q And given that they're well</p> <p>17 established, can you name all of the inherited</p> <p>18 genes that have been identified as being</p> <p>19 associated with an increased risk of ovarian</p> <p>20 cancer?</p> <p>21 A No, not -- I can't name them all off</p> <p>22 the top of my head, no. There's something in the</p> <p>23 neighborhood of 500 to -- 500 genes of strong</p> <p>24 association of cancer risk and progression, some</p>	<p style="text-align: right;">Page 349</p> <p>1 A Uh-huh.</p> <p>2 Q And the last sentence says, "Generally</p> <p>3 speaking, macrophages can increase inflammation</p> <p>4 or decrease inflammation, depending on the</p> <p>5 cytokines released."</p> <p>6 Correct?</p> <p>7 A Correct.</p> <p>8 Q So, with that statement, do you agree</p> <p>9 that inflammation can have both protumorigenic</p> <p>10 and antitumorigenic effects, depending on</p> <p>11 context, just as you state here for macrophages?</p> <p>12 MS. O'DELL:</p> <p>13 Object to the form.</p> <p>14 A No, I -- I would not agree with that.</p> <p>15 I -- I don't know of any evidence of that, that</p> <p>16 inflammation, as a physiological phenomenon, acts</p> <p>17 as an antitumor effect.</p> <p>18 MR. FERGUSON:</p> <p>19 Q Going to the next page, the page 11 --</p> <p>20 I'm trying to get through this</p> <p>21 hopefully within the next 15 minutes.</p> <p>22 -- under the role of inflammation in</p> <p>23 ovarian cancer --</p> <p>24 Are you with me there?</p>

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<p style="text-align: right;">Page 350</p> <p>1 A I am.</p> <p>2 Q And you're obviously talking about the</p> <p>3 role of inflammation there. Isn't it true that</p> <p>4 no published animal model has ever shown that</p> <p>5 inducing inflammation induces the development of</p> <p>6 ovarian cancer?</p> <p>7 MS. O'DELL:</p> <p>8 Object to the form.</p> <p>9 A We've been -- earlier today we were</p> <p>10 discussing some animal models as it relates to --</p> <p>11 MR. FERGUSON:</p> <p>12 Q Yeah. You and Miss Brown talked about</p> <p>13 a number of animal models.</p> <p>14 A Yeah.</p> <p>15 Q And -- and what I'm trying to ask you,</p> <p>16 is there any of those animal models or any others</p> <p>17 that have ever shown that inducing inflammation</p> <p>18 induces the development of ovarian cancer?</p> <p>19 A I didn't -- I didn't look specifically</p> <p>20 for an animal study of that type in the process</p> <p>21 of developing the report.</p> <p>22 Q Later down that page, you talk about</p> <p>23 two models. "The literature reviews as well as</p> <p>24 many direct studies feature the immune system as</p>	<p style="text-align: right;">Page 352</p> <p>1 anything on that, so that's -- that's fine.</p> <p>2 Let's move on.</p> <p>3 A Okay.</p> <p>4 Q I think you've stated earlier that your</p> <p>5 opinion in this case is based on the totality of</p> <p>6 what is included in the product, the talcum</p> <p>7 powder products. Is that correct?</p> <p>8 A Correct.</p> <p>9 Q So you're -- you cannot distinguish</p> <p>10 the -- the carcinogenicity of the constituent</p> <p>11 parts of the talcum powder products, correct,</p> <p>12 including the fragrance?</p> <p>13 MS. O'DELL:</p> <p>14 Object to the form.</p> <p>15 A I -- I was -- I was not asked to -- to</p> <p>16 provide that delineation. And, so, instead,</p> <p>17 subsequent to seeing some of the other expert</p> <p>18 reports, we began with talcum powder as a product</p> <p>19 and then have since learned more about the</p> <p>20 constituent components, including asbestos,</p> <p>21 fragrance, potential for heavy metals, which I</p> <p>22 understand or I've observed that there's a</p> <p>23 variety of testing documents that -- that show a</p> <p>24 variety of results.</p>
<p style="text-align: right;">Page 351</p> <p>1 being an important mediator of ovarian</p> <p>2 carcinogenesis via two models, chronic</p> <p>3 inflammation and incessant ovulation."</p> <p>4 Correct?</p> <p>5 A Correct.</p> <p>6 Q Is it your opinion that incessant</p> <p>7 ovulation is a form of chronic inflammation?</p> <p>8 A It is not.</p> <p>9 Q Isn't it true that there's no</p> <p>10 pathological evidence in humans that perineal</p> <p>11 talc users have ovarian inflammation?</p> <p>12 MS. O'DELL:</p> <p>13 Object to the form.</p> <p>14 A I'm thinking.</p> <p>15 I would have to review the --</p> <p>16 I'm sorry. That's -- it's --</p> <p>17 MR. FERGUSON:</p> <p>18 Q Okay.</p> <p>19 A I would -- again, I would have to look</p> <p>20 more carefully for that. I can't -- I can't name</p> <p>21 a study of that type right now.</p> <p>22 Q So I think you've said previously --</p> <p>23 Are you done looking?</p> <p>24 I understood you couldn't give me</p>	<p style="text-align: right;">Page 353</p> <p>1 So, to answer your question, I did not</p> <p>2 specifically evaluate the individual specific</p> <p>3 components in any -- in any individual product as</p> <p>4 it relates. Instead, remained focused on the</p> <p>5 mechanism for the complete -- complete product.</p> <p>6 MR. FERGUSON:</p> <p>7 Q And you've made reference to heavy</p> <p>8 metals throughout your testimony on occasion. Do</p> <p>9 you recall that?</p> <p>10 A I do.</p> <p>11 Q Do you have any opinions that any of</p> <p>12 these heavy metals contribute to the inflammation</p> <p>13 process that you've been talking about?</p> <p>14 A The -- to the inflammation --</p> <p>15 I'm not aware of any direct evidence</p> <p>16 for heavy metal contribution to the inflammation</p> <p>17 process that we've been discussing. Instead, the</p> <p>18 heavy metals, particularly chromium, caught my</p> <p>19 attention because of its well-established ability</p> <p>20 to directly damage DNA and, therefore, you know,</p> <p>21 potentially play a role in carcinogenesis.</p> <p>22 Q Do you have any knowledge or opinion</p> <p>23 about how much chromium you claim is in the -- in</p> <p>24 the body powder products?</p>

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<p style="text-align: right;">Page 354</p> <p>1 MS. O'DELL: 2 Object to the form. 3 A I wasn't asked to evaluate the amount 4 of chromium or whether it was sufficient for 5 damage. It was more reviewing. I would have to 6 defer to other experts who have done the testing 7 on the products. 8 MR. FERGUSON: 9 Q So you have no opinion on that? 10 MS. O'DELL: 11 Object to the form. 12 A I'm sorry. An opinion on the amount of 13 chromium? 14 MR. FERGUSON: 15 Q Correct. 16 A Again, I wasn't asked to generate such 17 an opinion. 18 Q I think -- I think I'm almost done. 19 Isn't it true that published data have 20 demonstrated that talc is not genotoxic and does 21 not cause mutations? 22 MS. O'DELL: 23 Object to the form. 24 A I'm not aware of a study that</p>	<p style="text-align: right;">Page 356</p> <p>1 talc with asbestiform bodies, I think would be 2 very reasonable to state that it has mutagenic 3 properties. 4 MR. FERGUSON: 5 Q And can you cite me any literature for 6 that? 7 A I would simply refer to the -- much of 8 the body of asbestos literature for the -- for 9 that. 10 MR. FERGUSON: 11 I think that's all I have. I'll turn 12 it over to someone else to ask some questions. 13 MS. BROWN: 14 Anybody with some more? 15 MS. O'DELL: 16 I'm going to take a break for a few 17 minutes. 18 VIDEOGRAPHER: 19 Going off the record. The time is 20 4:54 p.m. 21 (OFF THE RECORD.) 22 VIDEOGRAPHER: 23 We're back on the record. The time is 24 5:20 p.m.</p>
<p style="text-align: right;">Page 355</p> <p>1 specifically looked at the genotoxicity of -- of 2 talc. And I think it would certainly warrant 3 defining which type of talc and components 4 therein. But I'm -- I'm not aware of a study 5 that has concluded that there are no genotoxic 6 effects of any type of talc. 7 MR. FERGUSON: 8 Q Would you agree there's no evidence 9 that talc causes sister chromatid exchange or 10 unscheduled DNA synthesis? 11 MS. O'DELL: 12 Object to the form. 13 A I didn't -- I didn't review the 14 literature for those two specific phenomenon. I 15 would have to, again, specifically look or review 16 for that. 17 MR. FERGUSON: 18 Q So, as you sit here, you have no 19 opinion as to whether talc is or is not 20 mutagenic? 21 MS. O'DELL: 22 Object to the form. 23 A No. We've -- so talc in general, 24 particularly in its -- in its form of fibrous</p>	<p style="text-align: right;">Page 357</p> <p>1 EXAMINATION 2 BY MS. O'DELL: 3 Q Dr. Levy, I have just a few follow-up 4 questions for you. 5 I'm gonna ask you to turn to page 14 of 6 your report. 7 And earlier today -- 8 I'm going to ask, Doctor, if you could 9 put the exhibits in front of you, and we'll pull 10 those out. 11 But earlier today you were asked about 12 a letter from the FDA that was marked as Exhibit 13 Number 16, and if you could pull that out of your 14 stack there. And, specifically, if you'll turn 15 to page 4 of the letter. 16 And you'll recall that this letter was 17 written in 2014. Do you remember that? 18 A Yes. 19 Q And if you look, however, at page 4 of 20 the letter, it appears that the FDA's review of 21 the relevant toxicity literature stopped at the 22 year 2008. Fair? 23 MS. BROWN: 24 Objection to the form.</p>

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<p style="text-align: right;">Page 358</p> <p>1 MS. O'DELL: 2 Q Did the FDA's review of the toxicity 3 literature stop in 2008? 4 A Yes. 5 Q And if you look at page 14 of -- of 6 your report, your review of the literature 7 included multiple references that were published 8 after 2008? 9 MS. BROWN: 10 Form. 11 A That's correct. 12 MS. O'DELL: 13 Q And, in fact, you cited Shukla that was 14 published in -- 15 Was Shukla published in 2009? 16 A Yes. The reference is in the report to 17 2009. 18 Q Yes. 19 And, in addition to that, did you cite 20 other references in support of your opinion that 21 talc powder causes inflammation that were dated 22 and published after 2008? 23 A I did. 24 Q And, so, the suggestion by counsel for</p>	<p style="text-align: right;">Page 360</p> <p>1 Objection to the form of the question. 2 A Yes, we -- we had a discussion 3 regarding the results shown in Figure 3, the 4 level of exposure of talc as well as its 5 duration. Sorry. The talc dose as well as 6 duration. 7 MS. O'DELL: 8 Q And in the -- if you'll look at 9 Figure 1, Doctor, explain to us, please, what 10 Figure 1 describes in terms of the viability of 11 the cells at the 72-hour mark. 12 A So the -- so Figure 1 is a graph 13 describing percent cell viability versus the 14 different normal or variant cells at a 24-hour 15 and 72-hour time point, two different ovarian 16 cancer cell lines, as well as doses of talc from 17 zero micrograms per milliliter up to 500 18 micrograms per milliliter, and each of those is 19 applied. 20 And at the 72-hour time point in both 21 cell lines, OSE2a and GCA1 -- GC1a shows a 22 decrease in cellular viability that is 23 dose-dependent in each of the four cell lines. 24 Q Okay. And --</p>
<p style="text-align: right;">Page 359</p> <p>1 Johnson & Johnson that somehow the FDA had 2 reviewed the literature for toxicity up until the 3 date of this letter would have been incorrect? 4 MS. BROWN: 5 Objection to the form of the question. 6 A As -- as we discussed, the -- the 7 letter from the FDA dated April 1st, 2014, states 8 to include literature from 1980 to 2008. 9 MS. O'DELL: 10 Q Let me ask you -- 11 You can put that aside, Dr. Levy. 12 Thank you. 13 And I want to ask you to pull out of 14 the stack the Exhibit 17, which is the Buz'Zard 15 paper. 16 A I have it. 17 Q And if you'll turn to page 581. 18 A Okay. 19 Q And just to orient our discussion, 20 counsel for Johnson & Johnson suggested that -- 21 that this paper showed a decrease in reaction or 22 reactive oxygen species at the longest time 23 interval. Do you recall that discussion? 24 MS. BROWN:</p>	<p style="text-align: right;">Page 361</p> <p>1 A Sorry. Each of the two cell lines. 2 Q And is it fair to say that the reason 3 you don't see dose response, you know, at the -- 4 at the greatest magnitude is because the cells 5 essentially die? 6 MS. BROWN: 7 Objection to the form. 8 A Well, I would say if we consider the 9 results displayed in Figure 1 in relation to the 10 results displayed in Figure 3, an ex- -- an 11 explanation for the concentrating on the 500 -- 12 the highest dose, the 500 micrograms per 13 milliliter, in the talc exposure, the decrease in 14 cellular viability is an -- is an explanation -- 15 could be an explanation for the decrease in 16 reactive oxygen species. 17 MS. O'DELL: 18 Q Okay. Thank you, Doctor. 19 And if you'll put that aside and turn 20 to Exhibit 7, which was the Hamilton paper we 21 spent quite a lot of time on earlier. 22 Do you recall the -- that discussion 23 regarding the Hamilton paper? 24 A I do.</p>

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<p>1 Q And what was the purpose for which you 2 cited the Hamilton paper? 3 A That it was one of the available animal 4 studies looking at the effects of talc on a rat 5 ovary. 6 Q And did the paper show that there was a 7 increase in inflammation as result of talc? 8 A Yes, in the form of foreign body 9 granulomas observed in five of the injected 10 ovaries. 11 Q And you're looking at, I guess, that 12 last sentence on page 103 and carrying over to 13 the -- to the narrative on page 105? 14 A Cellular foreign body? 15 Q Yes. 16 A Foreign body granulomas without any 17 surrounding inflammation were seen in five of the 18 injected ovaries. And similar lesions were not 19 uncommonly noted in the supracapsular fat in the 20 connective tissue matrix of the capsule. 21 Q And if you'll look down in the 22 discussion section, Dr. Levy, the first paragraph 23 there in your -- where -- beginning 24 "Unfortunately," does it appear that talc also</p>	<p>1 principle been published in the peer-reviewed 2 literature? 3 A It has. 4 Q And, in regard to ovarian cancer, prior 5 to becoming involved in the litigation, did you 6 hold the opinion that inflammation was a part of 7 the development of ovarian cancer? 8 A Yes. 9 Q And has that been researched and that 10 research published in the peer-reviewed 11 literature? 12 A It has. 13 Q In the same way, has the fact that 14 talc, talcum powder, induces inflammation been 15 published in the peer-reviewed literature? 16 MS. BROWN: 17 Objection to the form. 18 A Yes. 19 MS. O'DELL: 20 Q And you were asked whether there was 21 evidence that talc caused inflammation in humans. 22 Do you recall that question? 23 A I do. 24 Q And based on your exhaustive review of</p>
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<p>1 induced fibrosis -- 2 MS. BROWN: 3 Objection to form. 4 MS. O'DELL: 5 Q -- in the rats? 6 A The manuscript makes the statement 7 that, "Unfortunately, bursal distention occurred 8 as an unforeseen complication" and further states 9 that this probably resulted from talc-induced 10 fibrosis and obliteration of the small channel 11 which normally allows communication between the 12 cavity where the ovary lies and the perineum. 13 Q And though the authors concluded that 14 neoplastic changes were not seen, the authors did 15 find evidence of inflammation in their study? 16 A That's correct. 17 Q Prior to becoming involved in the 18 litigation, Dr. Levy, did you hold the opinion 19 that inflammation is a cause of cancer? 20 A As -- as we've discussed earlier, I 21 certainly held the opinion that, you know, 22 inflammation is a significant and necessary 23 component of cancer progression. 24 Q And has that been -- that general</p>	<p>1 the literature, what evidence would you point to 2 undergirding your opinion that talc causes 3 inflammation in humans? 4 A I think considering the molecular 5 mechanism we were discussing of the recent paper 6 by Saed, et al., again, that we discussed earlier 7 today is a fairly in-depth set of experiments to 8 examine the specific inflammatory response 9 of -- of human cells to -- to talcum powder. 10 Q In addition to the Saed publications, 11 would you -- would you include the Shukla 2009 12 paper in your consideration of talc causing 13 inflammation in humans? 14 A Yes. 15 MS. BROWN: 16 Form. 17 MS. O'DELL: 18 Q You were asked about your methodology 19 numerous times today, and can -- would you 20 describe in -- in general the methodology you 21 have used in reaching your opinions in this case? 22 A Yes. To clarify or perhaps expand on 23 the earlier discussions, my methodology involved 24 a literature review to examine the totality of</p>

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<p style="text-align: right;">Page 366</p> <p>1 the information available to the role that talcum 2 powder plays in inflammation in ovarian cancer. 3 And, so, that methodology involved, 4 first, a review of the literature and then a 5 development of a report and then a synthesis of a 6 biologically plausible mechanism where the basis 7 of that plausibility was to ask if each of the 8 different component steps that are described in 9 that mechanism was supported by peer-reviewed 10 research. First, does talc cause inflammation? 11 Second, does inflammation cause cancer? And 12 then, third -- or does inflammation cause ovarian 13 cancer? And then, third, is there -- is that 14 supportive of a overall mechanism of cancer 15 progression and metastasis? 16 Q Can that methodology be replicated? 17 A Certainly. I think, you know, anyone 18 with a similar -- similar background and 19 experience who -- who undertook the same 20 activities would likely -- certainly likely come 21 up with the same -- same conclusions. 22 Q Did you rely on the IARC monograph in 23 relation to nickel, chromium, and cobalt in 24 reaching your opinions in this case?</p>	<p style="text-align: right;">Page 368</p> <p>1 Q Is this the Park paper that you 2 referenced -- 3 MS. BROWN: 4 Counsel, do you have a copy for us? 5 MS. O'DELL: 6 I don't. I'm assuming -- I don't think 7 Ken marked it, but I'm assuming he has a copy. 8 Q Is that the Park paper that you 9 referenced in your report, Dr. Levy? 10 A It is. 11 Q And if you'll turn to page 8 of the 12 paper, about midway down the first column, maybe 13 a little bit less, see the paragraph starting "We 14 did find an association"? Page 8. 15 A I'm looking for the page number. 16 Q Sorry. Let me give you a page number. 17 I'm not sure it has a page number. 18 A No, it doesn't. 19 Q Do you see the paragraph beginning "We 20 did find associations between overall cancer and 21 history of fibroid or ovarian cysts"? Do you see 22 that paragraph? 23 A Well, actually -- yes, I see that 24 paragraph.</p>
<p style="text-align: right;">Page 367</p> <p>1 MS. BROWN: 2 Objection to the form. 3 A I -- so the -- the number of IARC 4 publications were certainly in the material that 5 was reviewed for -- for my -- for my report. 6 MS. O'DELL: 7 Q Based on your review of the literature, 8 is it your opinion that nickel causes 9 inflammation? 10 A Yes. The IARC -- the -- the 11 characterization of those compounds, nickel as 12 well as chromium, among others, are -- would have 13 an inflammatory response. 14 Q You were asked questions earlier 15 today -- actually, not so much earlier -- a few 16 minutes ago regarding the Park paper. And you 17 cited the Park paper on page -- I think it was 8 18 of your report. 19 A Yes. 20 Q And let me show you what I'm marking as 21 Exhibit 22 to your deposition. 22 (DEPOSITION EXHIBIT NUMBER 22 23 WAS MARKED FOR IDENTIFICATION.) 24 MS. O'DELL:</p>	<p style="text-align: right;">Page 369</p> <p>1 Q If you'll look further, the sentence 2 beginning "This observation may suggest," do you 3 see that? 4 A Yes. Uh-huh. 5 Q And the paper says, "This observation 6 may suggest a possible additive or synergistic 7 effect on tumor- -- tumorigenesis influenced by 8 the proinflammatory milieu from an increased 9 burden in the number of benign conditions. 10 Increased risk of serous cancer, ovarian cancer, 11 women with other proinflammatory risk factors has 12 been reported -- reported, most notably in talc 13 users." 14 Do you see that? 15 A I do. 16 Q Is that the section you were thinking 17 of when you cited it in your report? 18 MS. BROWN: 19 Objection to the form. 20 A Yes, it is. 21 MS. O'DELL: 22 Q Let me ask you to -- a couple of other 23 final questions, Dr. Levy. 24 Excuse me. Give me one moment.</p>

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<p>1 In regard to opinions in relation to</p> <p>2 the pathology of ovarian tissue, would you defer</p> <p>3 to a gynecologist or gynecologic oncologist or a</p> <p>4 pathologist regarding that matter?</p> <p>5 A Yes, of course.</p> <p>6 Q You testified earlier today that you</p> <p>7 relied on the Longo testing in -- in reaching</p> <p>8 your opinions in this case.</p> <p>9 MS. BROWN:</p> <p>10 Objection to the form.</p> <p>11 MS. O'DELL:</p> <p>12 Q Did you rely on Dr. Longo's testing</p> <p>13 in -- in reaching your opinions in this case?</p> <p>14 A Yes. They were -- they were one of</p> <p>15 the -- among many of the manuscripts we've been</p> <p>16 discussing.</p> <p>17 Q Yeah.</p> <p>18 In fact, you cite Dr. Longo's report on</p> <p>19 page 15 of your report. Is that right?</p> <p>20 MS. BROWN:</p> <p>21 Objection to the form.</p> <p>22 A Yes.</p> <p>23 MS. O'DELL:</p> <p>24 Q And -- and in terms of Dr. Longo's</p>	<p>1 Q And did you have the opportunity to</p> <p>2 consider his report prior to finalizing your</p> <p>3 report?</p> <p>4 A I did.</p> <p>5 Q I have nothing further. Thank you.</p> <p>6 EXAMINATION</p> <p>7 BY MS. BROWN:</p> <p>8 Q Dr. Levy, would you take Exhibit 16</p> <p>9 out, please, the FDA's response to the citizens</p> <p>10 petition?</p> <p>11 A I have it.</p> <p>12 Q Counsel asked you some questions that</p> <p>13 involved questions that I asked you. Remember</p> <p>14 she asked you the lawyer for J & J didn't point</p> <p>15 out the articles that were reviewed from 1980 to</p> <p>16 2008 on page 4? Do you recall those questions</p> <p>17 from plaintiffs' counsel?</p> <p>18 A Yes.</p> <p>19 Q Would you look at the last page of the</p> <p>20 letter, page 6 of 7? I'd like to direct your</p> <p>21 attention to the second sentence on this page</p> <p>22 that begins "In consideration of your request."</p> <p>23 Do you see that?</p> <p>24 A I do.</p>
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<p>1 report, his findings of 37 of 56 historical talc</p> <p>2 samples being positive for asbestos and 41 of the</p> <p>3 42 samples tested containing fibrous talc,</p> <p>4 was -- was that information you had prior to</p> <p>5 reaching your opinions and finalizing your</p> <p>6 report?</p> <p>7 MS. BROWN:</p> <p>8 Objection to the form.</p> <p>9 A Yes.</p> <p>10 MS. O'DELL:</p> <p>11 Q And in relation to Dr. Crowley's report</p> <p>12 regarding the fragrance chemicals, do you defer</p> <p>13 to Dr. Crowley regarding his analysis of the</p> <p>14 fragrance chemicals?</p> <p>15 A Yes.</p> <p>16 Q And did you rely on the opinions he</p> <p>17 reached in relation to the fragrance chemicals in</p> <p>18 reaching your opinions in this case?</p> <p>19 A Yes. My -- my review of that just, in</p> <p>20 addition to deferring it, was -- just made the</p> <p>21 general -- or made the statement that I was in</p> <p>22 general agreement with his opinions in those</p> <p>23 matters, seeing as that's not a -- not an area of</p> <p>24 expertise of mine.</p>	<p>1 Q And it states, "In consideration of</p> <p>2 your request, we conducted an expanded literature</p> <p>3 search dating from the filing of the petition in</p> <p>4 2008 through January 2014. The results of this</p> <p>5 search failed to identify any new compelling</p> <p>6 literature data or new scientific data."</p> <p>7 Do you see that?</p> <p>8 A I see that.</p> <p>9 Q And putting together, then, the</p> <p>10 information from page 4 and page 6, you see that</p> <p>11 the FDA considered literature from 1980 to 2014.</p> <p>12 Is that correct?</p> <p>13 MS. O'DELL:</p> <p>14 Object to the form.</p> <p>15 A Yes, that is correct.</p> <p>16 MS. BROWN:</p> <p>17 Q And what the FDA concluded, contrary to</p> <p>18 your opinion here, Doctor, is that a cogent</p> <p>19 biological mechanism by which talc might lead to</p> <p>20 ovarian cancer is lacking; correct?</p> <p>21 MS. O'DELL:</p> <p>22 Object to the form.</p> <p>23 A That's in this --</p> <p>24 MS. BROWN:</p>

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<p style="text-align: right;">Page 374</p> <p>1 Q Directing your attention to page 4, 2 number 4, the conclusion regarding a cogent 3 biological mechanism lacking. Do you see that? 4 MS. O'DELL: 5 Object to the form. 6 A Yes. I see where they -- they made the 7 statement that cogent biological mechanism by 8 which talc might lead to ovarian cancer is 9 lacking and that exposure to talc does not 10 account for all cases of ovarian cancer. 11 MS. BROWN: 12 Q Next, Doctor, do you rely on the 13 findings of the Hamilton article in forming your 14 opinions in this case? 15 A Similar to as we've discussed, in a 16 portion, yes. 17 Q You, Dr. Levy, cannot point us to a 18 single paper showing an inflammatory response 19 leading to ovarian cancer in humans from talc 20 use. True? 21 A There is -- I do not know of a single 22 paper that -- in a controlled fashion in humans 23 provided talc exposure that then was -- 24 subsequently led to cancer in humans. That's</p>	<p style="text-align: right;">Page 376</p> <p>1 talc was causing in the body. True? 2 MS. O'DELL: 3 Object to the form. 4 A I'm aware of a number of studies that 5 looked at inflammatory response in model systems 6 and cell lines, and additional studies that 7 looked at inflammation in humans I believe were 8 referenced. 9 Certainly the Penninkilampi manuscripts 10 described inflammatory observations and -- as 11 well as the Buz'Zard and Lau were on human cells. 12 Q Dr. Levy, is it your testimony that the 13 Penninkilampi meta-analysis of prior 14 case-controlled studies demonstrated a 15 inflammatory response of -- from perineal use of 16 talc that led to ovarian cancer? 17 MS. O'DELL: 18 Object to the form. 19 A No. That's not my statement. It was 20 that those -- those papers reported an 21 inflammatory observation as part of those 22 studies. 23 MS. BROWN: 24 Q Not in the tissue from talc; right,</p>
<p style="text-align: right;">Page 375</p> <p>1 correct. 2 Q Controlled aside, you're not aware of 3 any observational case report, any kind of study 4 that shows talcum powder use causing an 5 inflammatory response leading to cancer in 6 humans; correct? 7 MS. O'DELL: 8 Object to the form. 9 A I would -- my review and development of 10 the biological plausibly -- plausible mechanism 11 examined literature that led to the conclusions 12 described in the report. I'm not aware of a -- 13 The human-based studies were all case 14 cohort and -- or case-controlled and cohort 15 studies that showed an association with talc 16 exposure and cancer, but I'm not aware of a 17 direct study. 18 MS. BROWN: 19 Q There have been some reports of alleged 20 findings of talc in tissues or in other parts of 21 the body. Are you familiar with those? 22 A Yes. 23 Q And you're not aware of any one of them 24 demonstrating an inflammatory response that the</p>	<p style="text-align: right;">Page 377</p> <p>1 Doctor? 2 MS. O'DELL: 3 Object to the form. 4 A It would be those studies in the meta 5 review were not examining the tissue content for 6 talc. So they're unable to make that 7 determination. 8 MS. BROWN: 9 Q So we must be missing. I'm -- what I'm 10 asking you is for any study at all in the whole 11 world that shows that talcum powder in somebody's 12 body causing an inflammatory response that led to 13 ovarian cancer. Can you name one? 14 MS. O'DELL: 15 Object to the form. 16 A I mean, we've -- we've discussed a 17 number of studies that described the risk and 18 association of talc in ovarian cancer. But the 19 limitation of the -- of your question or the 20 limitation of the studies relative to your 21 question is those particular studies may not have 22 also assessed the inflammatory response or an 23 inflammatory response, given the nature of the 24 studies.</p>

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<p style="text-align: right;">Page 378</p> <p>1 MS. BROWN:</p> <p>2 Q Well, we got one. We got the Heller</p> <p>3 study that purported to find talc in ovarian</p> <p>4 tissue; right?</p> <p>5 MS. O'DELL:</p> <p>6 Object to the form. Different --</p> <p>7 MS. BROWN:</p> <p>8 Counsel, it's form, please.</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form.</p> <p>11 A Yeah. What was the -- the Heller</p> <p>12 study, here it is.</p> <p>13 Yes, I recall our discussion of this</p> <p>14 paper.</p> <p>15 MS. BROWN:</p> <p>16 Q Right.</p> <p>17 And this study reported that there was</p> <p>18 no inflammatory response around the talc that</p> <p>19 they claimed to have found in the ovarian tissue.</p> <p>20 True?</p> <p>21 A They make those statements in the</p> <p>22 paper, but the -- the -- I would have some</p> <p>23 concern with the histological methods, but I</p> <p>24 would certainly defer to a pathologist in the</p>	<p style="text-align: right;">Page 380</p> <p>1 MS. O'DELL:</p> <p>2 Actually, that wasn't your question.</p> <p>3 But you've clarified it, so --</p> <p>4 A The -- so you're excluding -- are you</p> <p>5 excluding cell lines?</p> <p>6 MS. BROWN:</p> <p>7 Q Yeah. Human beings. Do you know of</p> <p>8 any study like Heller in human beings that</p> <p>9 purports to find talc in human women ovarian</p> <p>10 tissue that shows an inflammatory response?</p> <p>11 MS. O'DELL:</p> <p>12 Objection to form.</p> <p>13 A I'm not aware of a study showing that</p> <p>14 specifically.</p> <p>15 MS. BROWN:</p> <p>16 Q Counsel asked you some questions about</p> <p>17 nickel causing inflammation that leads to ovarian</p> <p>18 cancer. Do you recall those?</p> <p>19 MS. O'DELL:</p> <p>20 Object to the form.</p> <p>21 A No. I was asked if -- if heavy</p> <p>22 metal -- or components like nickel have been</p> <p>23 shown to have a potential inflammatory response.</p> <p>24 MS. BROWN:</p>
<p style="text-align: right;">Page 379</p> <p>1 sense of being able to determine the both</p> <p>2 presence of talc and the inflammatory response in</p> <p>3 that.</p> <p>4 Q So you have some critiques of the</p> <p>5 Heller study. Is that fair?</p> <p>6 MS. O'DELL:</p> <p>7 Object to the form.</p> <p>8 A I would say I would need a -- I would</p> <p>9 need a -- a -- I would need a further evaluation</p> <p>10 of the methodology for detecting both talc as</p> <p>11 well as inflammation in the same materials using</p> <p>12 the methods of the Heller paper.</p> <p>13 MS. BROWN:</p> <p>14 Q Are you aware of any other paper that</p> <p>15 you think is methodologically superior that shows</p> <p>16 the presence of talc in ovarian tissue exhibiting</p> <p>17 an inflammatory response?</p> <p>18 MS. O'DELL:</p> <p>19 Object to the form.</p> <p>20 A Well, we've discussed the rat studies.</p> <p>21 MS. BROWN:</p> <p>22 Q Human tissue. That's my question.</p> <p>23 A Human --</p> <p>24 Q Human tissue.</p>	<p style="text-align: right;">Page 381</p> <p>1 Q Uh-huh. Because you're not aware of</p> <p>2 any published scientific literature that shows</p> <p>3 heavy metals cause inflamma- -- inflammation that</p> <p>4 leads to ovarian cancer; right?</p> <p>5 A I wasn't asked to -- to review for</p> <p>6 that. I would state that there's a number of</p> <p>7 studies that show the role of metals --</p> <p>8 particularly chromium -- and its -- and its</p> <p>9 damaging effect on DNA, which I think by -- would</p> <p>10 certainly have both an inflammatory as well as</p> <p>11 carcinogenic effect.</p> <p>12 Q And we're here on an issue of ovarian</p> <p>13 cancer. And, as it relates to ovarian cancer,</p> <p>14 you're not aware of any scientific support for</p> <p>15 the proposition that heavy metals can lead to</p> <p>16 inflammation that causes ovarian cancer. Fair</p> <p>17 enough?</p> <p>18 A Well, I was -- certainly, I was asked</p> <p>19 to review the literature to develop a -- and</p> <p>20 develop conclusions of that literature as it</p> <p>21 related to a -- a potential or possible</p> <p>22 biological mechanism.</p> <p>23 In doing that, in part of that review,</p> <p>24 we certainly made the observation that talc and</p>

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<p>1 its components, as we discussed earlier, may</p> <p>2 have -- there's the possibility of having</p> <p>3 additional component effects, such as heavy</p> <p>4 metals and their effects, asbestiforms and their</p> <p>5 effects and the like; therefore, really</p> <p>6 considering the complete components of the</p> <p>7 product overall.</p> <p>8 Q And, as it relates to the testimony you</p> <p>9 just gave, you're talking about just a</p> <p>10 theoretical possibility; right?</p> <p>11 MS. O'DELL:</p> <p>12 Objection to form.</p> <p>13 A Sure. And, then, from that review</p> <p>14 developing a -- a conclusion of a biologically</p> <p>15 plausible mechanism.</p> <p>16 MS. BROWN:</p> <p>17 Q Has that conclusion been published in</p> <p>18 the peer-reviewed literature, Doctor?</p> <p>19 A No, it has not.</p> <p>20 Q And, in fact, as you -- all of the</p> <p>21 opinions that you gave here today, those opinions</p> <p>22 have not been published in the peer review</p> <p>23 literature. True?</p> <p>24 MS. O'DELL:</p>	<p>1 mineralogy of talc.</p> <p>2 Q And whether what Dr. Longo is finding</p> <p>3 in the samples that he tested is the asbestiform</p> <p>4 or nonasbestiform variety of the minerals, you</p> <p>5 would defer to others? Is that fair?</p> <p>6 A I'd certainly defer to Dr. Longo.</p> <p>7 Q And have you looked at any other</p> <p>8 testing of the samples that Dr. Longo has tested?</p> <p>9 MS. O'DELL:</p> <p>10 Object to the form. Vague.</p> <p>11 A Within the literature, there's -- there</p> <p>12 was a number of tables describing testing,</p> <p>13 described tests from previous testimony.</p> <p>14 MS. BROWN:</p> <p>15 Q Have you looked at the testing that</p> <p>16 public health authorities like the FDA have done</p> <p>17 on Johnson & Johnson's baby powder?</p> <p>18 A I believe some of that was provided,</p> <p>19 yes.</p> <p>20 Q Are you relying on any finding of</p> <p>21 asbestos from Dr. Longo in forming your opinions</p> <p>22 here today?</p> <p>23 A The --</p> <p>24 MS. O'DELL:</p>
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<p>1 Object to the form.</p> <p>2 A Not at this time.</p> <p>3 Q Counsel asked you some questions about</p> <p>4 Dr. Longo. Do you recall that?</p> <p>5 A Yes.</p> <p>6 Q You've done nothing to validate the</p> <p>7 findings that Dr. Longo writes about in his</p> <p>8 reports. Is that fair?</p> <p>9 A No, I have not done any experiments to</p> <p>10 validate those findings.</p> <p>11 Q Okay. Are you aware that some of the</p> <p>12 samples that Dr. Longo tests and purports to find</p> <p>13 asbestos were purchased off of eBay?</p> <p>14 MS. O'DELL:</p> <p>15 Misstates -- well --</p> <p>16 A My review of the report, I was -- did</p> <p>17 not include the -- I guess the specific history</p> <p>18 of each of the samples.</p> <p>19 MS. BROWN:</p> <p>20 Q Do you understand that asbestos -- that</p> <p>21 minerals like tremolite or anthophyllite, they</p> <p>22 exist in both the asbestiform and nonasbestiform</p> <p>23 way?</p> <p>24 A I would defer to other experts on the</p>	<p>1 Object to the form.</p> <p>2 A The inclusion of the asbestos, again,</p> <p>3 as -- as -- as we've discussed a few times today,</p> <p>4 the conclusion I developed from the report were</p> <p>5 not dependent or independent of any one or</p> <p>6 another component of -- of the talcum powder.</p> <p>7 As we discussed a bit ago, the presence</p> <p>8 of asbestos as a known inflammatory mediator, as</p> <p>9 well as potential carcinogen, I think just helps</p> <p>10 lend additional support to the biological</p> <p>11 plausibility of the mechanism. But I think that</p> <p>12 biological mechanism is not dependent on the</p> <p>13 presence of asbestos.</p> <p>14 MS. BROWN:</p> <p>15 Q Other than plaintiffs' expert,</p> <p>16 Dr. Longo, are you relying on anything else to</p> <p>17 support the potential for asbestos in baby</p> <p>18 powder?</p> <p>19 MS. O'DELL:</p> <p>20 Object to the form.</p> <p>21 A There's -- so I saw reference to</p> <p>22 asbestos content in some of the other literature</p> <p>23 that was reviewed during the time, and, so, there</p> <p>24 were other publications that made mention of the</p>

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<p style="text-align: right;">Page 386</p> <p>1 asbestos content in talc during the overall 2 review. 3 MS. BROWN: 4 Q Sitting here today, are you aware 5 whether or not that was Johnson & Johnson's 6 cosmetic talc? 7 MS. O'DELL: 8 Object to the form. 9 A I would have to look closely. I'm not 10 aware of that specifically. 11 MS. BROWN: 12 Q Counsel asked you some questions about 13 Dr. Crowley and whether or not you were relying 14 on the opinions he reached. Do you remember 15 those questions? 16 A I do. 17 Q What opinions did Dr. Crowley reach on 18 which you rely? 19 A Dr. Crowley performed an analysis of 20 the fragrance components and made assessments of 21 the individual chemical components and their 22 relationship to -- or I should say their -- their 23 inclusion on various lists for their -- their 24 chemical properties or safety. And in most -- in</p>	<p style="text-align: right;">Page 388</p> <p>1 opinion is independent of Dr. Crowley's findings. 2 Is that fair? 3 MS. O'DELL: 4 Objection to form. Vague. 5 A Well, my -- my -- my opinion, again, 6 similar to -- as we've been discussing that, it 7 considers the totality of the information 8 available, including Dr. Crowley's report, but 9 does not rely on any one specific report or 10 otherwise. 11 And, so, the -- again, restating 12 similar to the asbestos, the presence of 13 potential irritants as another component in 14 the -- in the product just provides additional 15 support for that inflammatory mechanism playing a 16 significant role. 17 MS. BROWN: 18 Q If none of the chemicals Dr. Crowley 19 identified were present in baby powder, would you 20 hold the same opinion of biological plausibility? 21 A I would. 22 Q If no asbestos was present in baby 23 powder, would you hold the same opinion on 24 biological plausibility?</p>
<p style="text-align: right;">Page 387</p> <p>1 the majority of cases, the chemicals were not 2 listed. In a number of cases, there were large 3 numbers of chemicals listed as either irritants 4 and, therefore, able to cause inflammation, or, 5 in a few cases, as potential carcinogens. 6 And, so, it was that review of that 7 information, similar to our discussions around 8 asbestos, that I included or agreed with his 9 opinions regarding that on the last paragraph or 10 close to the last paragraph of the report that 11 stated I was just in agreement that these -- that 12 those chemicals contribute to the inflammatory 13 properties observed. 14 Q Do you know in what quantity the 15 chemicals Dr. Crowley identifies are present, if 16 at all, in Johnson & Johnson's products? 17 A No. I wasn't asked to provide that 18 review. I would defer to Dr. Crowley's report 19 regarding any quantitative analysis of those 20 chemicals. 21 Q And, as it relates to your opinion, 22 Dr. Levy, it makes no difference whether 23 Dr. Crowley's list has ten chemicals in 24 Quantity X or five chemicals in Quantity Y. Your</p>	<p style="text-align: right;">Page 389</p> <p>1 A Yes. 2 MS. BROWN: 3 No further questions. Thank you. 4 MS. O'DELL: 5 I have just one follow-up. 6 Or do you have anything -- 7 MR. FERGUSON: 8 Nothing further. 9 MS. O'DELL: 10 Excuse me. I'm sorry. 11 EXAMINATION 12 BY MS. O'DELL: 13 Q Dr. Crowley, are your opinions in this 14 case contained in your report as well as in the 15 testimony that you've given here today? 16 A You said Dr. Crowley. 17 Q Oh. Excuse me. Sorry. I had 18 Dr. Crowley on my mind. 19 Dr. Levy -- 20 It's getting late in the day. 21 Dr. Levy, are your opinions in this 22 case expressed in your report and your testimony 23 today? 24 A Yes.</p>

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<p>Page 390</p> <p>1 Q And do you hold those opinions to a</p> <p>2 reasonable degree of scientific certainty?</p> <p>3 A Yes.</p> <p>4 MS. O'DELL:</p> <p>5 I have nothing further.</p> <p>6 MS. BROWN:</p> <p>7 Thanks for your time, Doctor.</p> <p>8 I think we're off the record.</p> <p>9 VIDEOGRAPHER:</p> <p>10 We're off the record. The time is</p> <p>11 6 p.m.</p> <p>12 (Deposition concluded at 6:00 p.m.)</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>Page 392</p> <p>1 ERRATA PAGE</p> <p>2</p> <p>3 I, SHAWN LEVY, Ph.D., the witness herein,</p> <p>4 have read the transcript of my testimony, and the</p> <p>5 same is true and correct, to the best of my</p> <p>6 knowledge, with the exceptions of the following</p> <p>7 changes noted below, if any:</p> <p>8 Page/Line Word(s) to be changed/reason Correct Word</p> <p>9 _____</p> <p>10 _____</p> <p>11 _____</p> <p>12 _____</p> <p>13 _____</p> <p>14 _____</p> <p>15 _____</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23 SHAWN LEVY, Ph.D.</p> <p>24</p>
<p>Page 391</p> <p>1 CERTIFICATE</p> <p>2</p> <p>3 I do hereby certify that the above and</p> <p>4 foregoing transcript of proceedings in the matter</p> <p>5 aforementioned was taken down by me in machine</p> <p>6 shorthand, and the questions and answers thereto</p> <p>7 were reduced to writing under my personal</p> <p>8 supervision, and that the foregoing represents a</p> <p>9 true and correct transcript of the proceedings</p> <p>10 given by said witness upon said hearing.</p> <p>11 I further certify that I am neither of</p> <p>12 counsel nor of kin to the parties to the action,</p> <p>13 nor am I in anywise interested in the result of</p> <p>14 said cause.</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19 LOIS ANNE ROBINSON, RPR, RMR</p> <p>20 REGISTERED DIPLOMATE REPORTER</p> <p>21 CERTIFIED REALTIME REPORTER</p> <p>22</p> <p>23</p> <p>24</p>	<p>Page 393</p> <p>1 DECLARATION OF WITNESS</p> <p>2</p> <p>3 I, the undersigned, declare under penalty</p> <p>4 of perjury that I have read the foregoing</p> <p>5 transcript, and I have made any corrections,</p> <p>6 additions, or deletions that I was desirous of</p> <p>7 making; that the foregoing is a true and correct</p> <p>8 transcript of my testimony contained herein.</p> <p>9 EXECUTED this _____ day of _____,</p> <p>10 2019, at _____,</p> <p>11 (City) (State)</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16 _____</p> <p>17 SHAWN LEVY, Ph.D.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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19:7 20:4,9	373:10 390:11			
21:5 22:14	6:00 390:12			
55:11 63:20,24	60 319:19			
64:19 200:9	60606-9997 3:9			
201:8,9 203:2	6950 3:8			
357:15,19				
372:16 373:10	7			
374:1,2	7 4:4 5:6 30:12			
4:54 356:20	30:13 71:24			
40 161:23 337:3	72:8 73:8			
337:10,20	185:9 194:14			
40,000 338:5	334:13 337:1			
400 2:10	361:20 372:20			
41 371:2	7-337:13			
42 221:9,15,18	72 5:12			
371:3	72-hour 360:11			
45 238:1	360:15,20			
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Exhibit 17

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

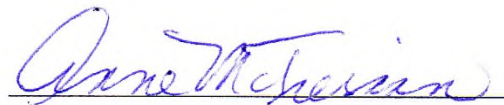
**IN RE JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES,
AND PRODUCTS LIABILITY
LITIGATION**

MDL NO. 16-2738 (FLW) (LHG)

THIS DOCUMENT RELATES TO ALL CASES

**RULE 26 EXPERT REPORT OF
ANNE MCTIERNAN, MD, PHD**

Date: November 16, 2018



Anne McTiernan, MD, PhD

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Mandate

I have been retained to review the current state of the scientific literature regarding talcum powder products and opine on whether those products cause ovarian cancer. When I refer to talc or talcum powder products in this report, I am referring to commercially available talcum powder products and all constituent elements contained within. All my opinions in this report are based upon a reasonable degree of scientific and medical certainty. My time is billed at \$450 per hour for the literature review and preparation of this report. I have not previously provided expert testimony in legal cases.

Credentials, Expertise, and Experience

I am a Full Member at the Fred Hutchinson Cancer Research Center in Seattle, Washington, Division of Public Health Sciences, Program in Epidemiology. I am also a Full Research Professor at the University of Washington School of Public Health, Department of Epidemiology, and the University of Washington School of Medicine, Department of Medicine, Division of Geriatrics. I am an elected member of the American College of Epidemiology, the Obesity Society, and the American College of Sports Medicine. From 2002-2012, I directed the Fred Hutchinson Cancer Research Center's Prevention Center.

I have received several prestigious awards for my research work including: the American College of Sports Medicine Wolffe Lecture, 2018, the American College of Sports Medicine Citation Award, 2012; the McDougall Mentoring Award, Fred Hutchinson Cancer Research Center, 2011; Komen for the Cure Scientific Advisory Council/Komen Scholars, 2010-2012; the University of Washington Roger E. Moe Award for Translational Research 2009; and the Joan P. Liman MD Award, Recipient, New York Medical College, 1989.

I received my PhD in Epidemiology in 1982 from the University of Washington, and my MD degree in 1989 from New York Medical College. I completed Internal Medicine residency training from the University of Washington in 1992. For the past 25 years, I have focused on epidemiologic research, primarily in cancer and women's health. My research studies used the methodology employed in the talcum powder products and ovarian cancer studies, namely, case-control studies, cohort studies, and meta-analyses. In addition, I have had leadership positions for several randomized controlled trials

testing interventions to prevent cancer. I have published over 400 scientific manuscripts in peer-reviewed medical and scientific journals, have contributed to several academic texts, and have edited two academic texts.

I have held several leadership positions in scientific U.S. Government work. Most recently, I was a member of the 2018 U.S. Department of Health and Human Services Physical Activity Guidelines Advisory Committee and was a member of the 2008 U.S. Department of Health and Human Services Physical Activity Guidelines Advisory Committee. I served as chair of the Cancer subcommittees for both Committees. I have served on, or chaired, grant review panels for the U.S. Department of Defense Congressionally Directed Medical Research Programs and the National Institutes of Health, and serve as a program reviewer for NCI intramural epidemiologic research branches and for NCI comprehensive cancer centers.

I have served on editorial boards for the American Association for Cancer Research Cancer Prevention Journal, the Journal of Women's Health, and Medscape Women's Health. I have reviewed manuscripts for over a dozen prestigious journals including: JAMA, Journal of the National Cancer Society, Archives of Internal Medicine, American Journal of Epidemiology, Annals of Internal Medicine, European Journal of Cancer, British Journal of Cancer, Cancer Causes & Control, Cancer Epidemiology Biomarkers & Prevention, Annals of Epidemiology, Epidemiology, and Nutrition.

My research funding has been provided by the U.S. National Cancer Institute, the National Institutes of Health, the National Heart Lung & Blood Institute, Komen for the Cure, the Breast Cancer Research Foundation, National Cancer Institute Canada, and various pharmaceutical companies and other foundations. I have been Principal Investigator of several randomized clinical trials testing effects of various agents in relation to prevention of breast and other cancers, including exemestane, raloxifene, tamoxifen, aspirin, and vitamin D. In addition, I have been Principal Investigator of four randomized clinical trials testing effects of weight loss and exercise on biomarkers of breast and other cancers. I am co-investigator of a pending National Cancer Institute funded trial testing the effect of exercise on quality of life in women with ovarian cancer. I was Principal Investigator of the Seattle site of a prospective cohort study of 1100 breast cancer survivors that investigated associations of hormones, inflammation, diet, exercise, obesity, and breast cancer survival. I was Principal Investigator of a case-control study of thyroid cancer and hormones in women, and co-investigator of a case-control study of

breast cancer in men. I have published on data from other case-control studies including studies on breast cancer, pituitary tumors, melanoma, and colorectal adenomas. I have collaborated in several prospective cohort studies, resulting in lead, senior, and co-authorship of several epidemiologic manuscripts. These included the Women's Health Initiative Observational Study, the Tromso study, the Carotene and Retinol Efficacy Trial cohort, the VITAL cohort, and the Pancreatic Cancer Cohort Consortium.

While my major focus is in epidemiology of breast cancer, I have also published on ovarian cancer, on gynecologic cancers in general, and on women's cancers, as described below, as well as on colorectal, pancreas, melanoma, and prostate cancers. In my randomized clinical trials and prospective cohort studies, I have investigated the effects of weight loss and exercise on biomarkers of inflammation, which is highly relevant to the topic of this report, because inflammation may be one mechanism linking talcum powder products exposure and risk of ovarian cancer.

My international work in epidemiology has included work with the International Association for Research in Cancer (IARC), the World Cancer Research Fund, and the Norwegian Tromso and EBBA studies. For IARC, I chaired a working group on mechanisms for a monograph on obesity, physical activity, and cancer risk (IARC Handbook of Cancer Prevention 2002: Physical Activity and Weight Control, 2000-1). For the World Cancer Research Fund, I am a member of the advisory panel of experts that guides interpretation of meta-analyses and systematic reviews of nutrition, physical activity, obesity, and risk for many cancers including ovarian cancer (<http://wcrf.org/sites/default/files/Ovarian-Cancer-2014-Report.pdf>).

From 1992 to 1997, I was the Project Director for clinical work at the Women's Health Initiative Clinical Coordinating Center. I held this role from the inception of the Women's Health Initiative, and therefore directed all aspects of development and implementation of the three clinical trials and observational study. This included development of questionnaires and protocols. Of interest to ovarian cancer and talcum powder products, one of the Women's Health Initiative questionnaires includes questions about use of talcum powder products. Furthermore, ovarian cancer was one of the primary cancers included as an outcome in this study. As Project Director, I oversaw development of the protocol and procedures for ascertainment and adjudication of cancer outcomes, including ovarian cancer. When I stepped down as Project Director (to lead my own National Cancer Institute funded studies), I retained leadership of

the outcomes work for the Women's Health Initiative through 2005. This outcomes work entailed identifying cases of specific diseases such as cancer (including ovarian), collecting medical records, and classifying cases according to standardized criteria.

Although I have not personally conducted research on talcum powder products use and risk for ovarian cancer, I have published several manuscripts on gynecologic cancers, including prevention of ovarian cancer in women at high genetic risk, as well as effects of weight and exercise on risk for ovarian cancer and on survivorship in ovarian cancer patients. In addition, I am co-investigator of a National Cancer Institute grant to test an exercise intervention on quality of life in women with ovarian cancer.

While my expertise is in the area of epidemiology, primarily in women's health and cancer research, I regularly consider the reports and studies from different scientific and medical fields including pathology, oncology, gynecology, physiology, molecular biology, and toxicology, and therefore, I have experience and expertise to consider evidence presented by experts in these fields, as I do when I prepare scientific manuscripts and grant proposals, when I review grants and manuscripts for government and private funding agencies, and when I do peer-reviewing for scientific and medical journals. Attached as Exhibit A to this report is a current copy of my curriculum vitae.

Overall Approach

The foundation for this report is based upon my education, expertise, and years of experience in designing, conducting, and interpreting epidemiologic studies, as well as my medical training. I drew upon my years of experience with synthesizing and interpreting large numbers of epidemiologic studies for comprehensive reports including work for the U.S. government, the World Health Organization International Agency for Research on Cancer (IARC), and the World Cancer Research Fund. My opinions are based on the published epidemiologic evidence including original case-control and cohort studies, systematic reviews, meta-analyses, and pooled analyses on the topic of talcum powder products exposure and risk of ovarian cancer. In reviewing the epidemiologic literature, I used my experience as a researcher in evaluating study quality, and in determining evidence of association between talcum powder products and ovarian cancer in terms of estimated size of the effect and statistical significance. I drew upon my 36 years as a PhD-trained epidemiologist and 26 years as an MD-trained clinical scientist.

In developing my opinions in this report, I applied the same rigor and standards as I utilize in my academic and research work. In addition to my review of epidemiologic studies, I also considered and reviewed clinical, pathological, and biologic and mechanistic evidence regarding talcum powder product exposure and ovarian cancer development.

Executive Summary

This review assessed relevant published epidemiologic evidence on the association between use of talcum powder products in the genital/perineal area and risk of developing epithelial ovarian cancer. My review, as discussed more fully in this report, included 38 publications in Medline referenced scientific journals. Of these papers, 28 presented data from case-control studies(1-28), 5 presented results from 3 cohort studies(29-33), 7 were meta-analyses of all epidemiologic studies up to a set date(11, 22, 34-38), and 1 was a pooled analysis of 8 case-control studies(39). All of these form the basis for the conclusions below. The meta-analyses, which included data summarized from all published case-control and cohort studies, consistently showed that ever use of talcum powder products in the genital/perineal area is associated with a statistically significant 22 - 31% increased risk of developing epithelial ovarian cancer overall compared with never-users. Further, the meta-analyses found a statistically significant 24 – 32% increased risk of developing serous ovarian cancer—the most common subtype of epithelial ovarian cancer—in women who had ever used talcum powder products compared with never-users. The pooled analysis, which included data from 5 previously published and 3 unpublished case-control studies, found similar statistically significant increased risks for overall epithelial ovarian cancer and serous ovarian cancer (24%). The two most recent meta-analyses, and the pooled analysis, found evidence of relationships between increasing amount of exposure to talcum powder products in the perineal/genital area (including frequency, years of use, and estimates of lifetime applications) and increased risk of developing epithelial ovarian cancer (i.e., dose-response relationships).

Published laboratory and clinical studies on talc exposure and ovarian carcinogenesis have shown that in humans, talc can migrate from the perineum to the ovaries and that it can cause an inflammatory response. Elevated levels of biomarkers of inflammation (such as cytokines), as well as oxidative stress, provide biologically plausible pathways by which talcum powder product exposure can induce neoplastic transformation and result in ovarian cancer.

Given the frequency with which asbestos, a known carcinogen has been found in cosmetic and personal-use talc products, I reviewed the literature on the epidemiology of asbestos and risk of ovarian cancer. Due to the presence of not only asbestos but fibrous talc, heavy metals, and fragrance, I also reviewed literature on the carcinogenic properties of these constituents. IARC noted in its 2012 report that a causal association between exposure to asbestos and cancer of the ovary was clearly established.(40,

41) IARC has classified asbestos and talc containing asbestiform fibers grown in an asbestiform habit as Class 1 carcinogens(40, 42). Talc fibers grown in an asbestiform habit are often referred to as “fibrous talc.” The elongated features of fibrous talc have many of the carcinogenic properties of asbestos that are known to cause an inflammatory process.(40) The additional chemicals present in talcum powder products discussed above were also classified by IARC to be carcinogenic(40), contributing to the biologically plausible mechanisms to explain the carcinogenic effects of talcum powder products.

The epidemiologic evidence in total, along with the biological and pathological evidence, fits virtually all of the Bradford Hill aspects of causation(43), namely: strength, consistency across populations, temporality, biologic gradient (dose-response), plausibility, coherence, and analogy. The weight of the evidence related to genital use of talcum powder products and ovarian cancer development demonstrates a consistent increased risk. There are many instances in which relative risks less than 1.5 are widely accepted within the scientific community as being causative and have strong public health and clinical ramifications, as I point out in the report. Given the high prevalence of use of talcum powder products (as much as half of women in some studies), a relative risk/odds ratio in the range observed in these studies can have profound effects on clinical events and public health.

In my opinion, as an epidemiologist and physician, stated to a reasonable degree of medical and scientific certainty, use of talcum powder products, including Johnson & Johnson Baby Powder and Shower to Shower, in the genital/perineal area can cause ovarian cancer. I base this opinion on the statistically significant elevated risk estimates (relative risk, odds ratios) seen when the epidemiologic data are combined, the pathological evidence, the consistency of results across geographic areas and in different race/ethnic groups, the evidence of a positive dose-response effect, and the plausible biological mechanisms.

The Science of Epidemiology

Epidemiology is the science of diseases in human populations. Epidemiologists study patterns of disease occurrence to determine causes of the disease of interest, with an aim of finding ways to prevent the disease from occurring. Epidemiological research describes and seeks to explain the distribution of health and disease within human populations. Its methods are based mainly on comparative observations made at the level of individuals within populations. This type of investigation is known as observational. By relating differences in circumstances and behavior to differences in the incidence of disease, associations are identified that may or may not be causal.

In epidemiological studies, an 'exposure' is a factor or condition that may or may not influence the risk of disease. For assessing effects of some exposures, epidemiologists may employ randomized controlled clinical trials, but for exposures that have possible adverse effects with little known benefit, such studies would be unethical. For example, the effects of vitamin supplements have been tested in large-scale clinical trials to determine effects on risk for several cancers. This was considered ethical because the expectation was that the vitamin supplements could have benefit, and were unlikely to have risk, for study participants. For toxicological exposures, however, with little expectation of benefit to offset possible adverse effects, observational studies will usually be the only available epidemiological evidence.

Much public health knowledge derives from epidemiological studies. For example, observational epidemiological studies show us that individuals who drink excessive amounts of alcohol have a high risk for developing liver failure and other diseases. Such studies have shown that persons with obesity have a high risk for developing diabetes and that smokers have high risk for developing lung cancer. Similarly, the effects of toxic agents on risk for several diseases have been identified through observational epidemiological studies. Examples include the effect of lead paint on cognitive development in children; the effect of radium exposure on bone health, blood abnormalities, and cancers; and the effect of second hand smoke on risk for lung cancer in nonsmokers.

The associations between talcum powder product use and risk for ovarian cancer have been studied only in two types of epidemiologic studies—case-control and cohort—and therefore this description of epidemiologic methodology below is limited to those types of studies.

Terminology in Epidemiological Studies

Disease incidence: The incidence of a disease is the number of new cases that occur. An incidence rate is the number of new cases that occur per number of persons over an interval of time. Typically, for cancer, incidence rates per 100,000 individuals per year are determined. The incidence rate for ovarian cancer in the U.S. is approximately 11.7/100,000 women/year (<https://seer.cancer.gov/statfacts/html/ovary.html>).

Risk: The risk of a disease refers to likelihood of its occurrence. In epidemiological studies, risk is usually used in relative terms, that is, the risk of developing cancer in one group versus the risk in another group. In cancer epidemiology, the risk almost exclusively refers to risk of incident cancer, that is, risk of a new cancer occurrence.

Risk factor: The World Health Organization defines a risk factor as any attribute, characteristic or exposure of an individual that increases the likelihood of developing a disease or injury (http://www.who.int/topics/risk_factors/en/). Risk factors can be inherent, such as sex, age, and genetics; lifestyle-related such as diet, physical activity, or smoking; health related such as menstrual factors, reproductive history, or history of infectious diseases; toxic exposures such as minerals, metals, chemicals, or radiation; or medical, such as use of particular medications.

Exposures: In epidemiological studies, an ‘exposure’ is a factor or condition that may increase or decrease the risk of disease. In this report, use of talcum powder products is the ‘exposure’ investigated. Self-reporting of exposure could result in incomplete information. Some women may over-report use of personal products, while others may not recall whether they used the products, how often or at what quantity they used them, or for how long they continued using them. Studies in which participants are queried by trained interviewers may be able to obtain information in greater detail than when participants complete questions on a form.⁽⁴⁴⁾ However, women may be reluctant to relay sensitive personal information to an interviewer as opposed to a self-administered form.⁽⁴⁴⁾ This type of

systematic bias, however, would underestimate the relative risk, suggesting that effects of talcum powder product use in the perineal area may be stronger than reported in epidemiologic studies.

Association: Epidemiologists use the term association to describe how a disease occurrence varies as a result of the effect of an exposure. A positive association indicates that the exposure increases risk of the outcome; a negative association indicates that the exposure decreases risk of the outcome.

Etiology: The etiology is the cause or origin of a disease or condition.

Multi-factorial etiology: Very few cancers occur as a result of only one cause. Most, on the other hand, have several likely causes, each with different levels of effect. The most common risk factor for cancer is age, as older persons have increased risk for developing most of the common cancers. So, even though certain human papilloma viruses increase risk for head and neck cancers, their effect is most often seen with increasing age despite individuals acquiring the virus at a young age. For some cancers, exposures add to the effects of other exposures, or even multiply their effects. For example, both smoking and alcohol use increase risk for squamous cell carcinoma of the esophagus, but individuals who both smoke and drink have a risk of this cancer that is greater than what would be expected by adding the effects of the two exposures.

Latency period: The length of time between when a person is exposed to a causal agent and when their cancer is first diagnosed is called the latent period. This period is typically years to decades. For exposures that continue over time, it may not be possible to determine the latency period of that cancer.

Relative risk, odds ratio, and hazard ratio: The strength of a relationship between an exposure and the occurrence of disease is commonly expressed in terms of relative risk. In cohort studies, relative risk is the ratio of risk (or incidence) of a disease among people with an exposure to that among people without that exposure. In cohort studies, the hazard ratio can be used, and is the chance of an event occurring in one group (exposed) divided by the chance of the event occurring in another group (non-exposed). In case-control studies, the odds ratio is used, which is the ratio of the odds of exposure among cases to the odds of exposure among controls. Relative risks, odds ratios, and hazard ratios

above 1.0 indicate an increased risk, while those below 1.0 imply a protective effect. Therefore, a relative risk of 1.3 represents a 30% increased risk.

Statistical analyses: Epidemiologists use several types of statistical analyses to determine the size and significance of relationships among variables in sets of data. The most common in observational studies are the relative risk, odds ratio, and hazard ratio. These estimates are based on individual studies, or on meta-analyses, which are based on data from multiple studies. To determine the likelihood of these being true estimates of risk, rather than just occurring by chance, epidemiologists determine the statistical significance. For the relative risk, odds ratio, and hazard ratio, we calculate a confidence interval (CI), which shows the range of values that the true risk estimate likely represents. Most commonly, we use 95% CI, which means we are 95% sure that a true relative risk or odds ratio lies within that interval of numbers. If a confidence interval includes the number 1.0, then we say the association between the exposure and the disease could be null. Some epidemiologists consider a CI that has 1.0 at one end of the range to be of “marginal statistical significance.” A similar statistic is the p-value, which estimates how likely the observed association is likely due to chance. Epidemiologists often consider a p-value less than or equal to 0.05 as “statistically significant,” and often describe p-values between 0.05 and 0.09 as “marginally statistically significant.” However, the term just refers to the likelihood of a chance finding.

Both confidence intervals and p-values depend largely on the size of the population studied. If a relative risk/odds ratio indicates an effect that is consistent across studies, or that is large, we are less likely to reject the likelihood of true association, even if the confidence interval includes 1.0 or if the p-value is greater than 0.05.

Sample size: Because development of cancer can be a random event, epidemiologists strive to determine whether an association between an exposure and disease could have occurred by chance. If the study is designed appropriately, the chance of random-ness explaining observed associations is lessened. The number of cases of cancer within the study is a critical element to determining likelihood of causality.

Standardized incidence ratio and standardized mortality ratio: In some epidemiologic studies, only highly exposed persons are available for study. This is a common occurrence in studies of occupations with high levels of exposures to carcinogens, such as asbestos. Researchers typically then compare the incidence (or mortality) in the exposed cohort with the general population from which the exposed cohort is drawn. The standardized incidence ratio compares the actual versus expected number of cases of a disease, using the population data to determine expected numbers. Similarly, the standardized mortality ratio compares actual versus expected numbers of cause-specific or overall deaths. The standardized incidence ratio and standardized mortality ratio are similar to relative risks, and 95% confidence intervals are often presented.

Dose-response: “Dose response” began as a medical concept where it denotes a change in the effect of a medication or treatment according to the dose used. This concept can be applied to any exposure, including potentially toxic agents such as talcum powder products. The demonstration of a biological gradient adds weight to evidence that an exposure may be causal.

Dose response effects may be linear, where an increase in the exposure increases risk of disease at each level of increase in the exposure. A common example is the relationship between average packs/day and years of cigarette smoking and risk for lung cancer. Alternatively, there may be a ‘threshold’ below which there is no effect seen, but above which there is an effect. An example is the association between exposure to menopausal hormone therapy; use for short periods has little effect on risk of breast cancer, but risk consistently increases for five years’ or longer use.

Alternatively, the effect may be to influence risk one way at both low and high levels of exposure, but the other way at intermediate levels of exposure, shown as ‘J’- or ‘U’-shaped curves. In such cases, the exposure is evidently beneficial or harmful only within certain ranges. For example, intake of alcohol at small amounts has been related in some studies to lower risk of cardiovascular disease, whereas heavy intake increases risk.

Some exposures that are continuous variables are often reported in discrete categories. Although this is done for statistical reasons and can make effects easier to detect, the number and location of category boundaries may obscure the true relationship between exposure and the outcome, and non-linear effects of exposure may be missed if inappropriate categories are used.

Bias: A systematic error in the design, recruitment, data collection or analysis that results in a mistaken estimation of the true effect of the exposure and the outcome.

Confounding: This type of bias occurs when a third variable interferes with a true relationship between an exposure and an outcome. A confounding variable is one that is related to the risk of disease and to the exposure. It is not by itself a cause of the disease and does not lie in the pathway between the exposure and disease. A classic example is that individuals who report carrying matches in their pockets are more likely to develop lung cancer than individuals who do not carry matches. However, the true relationship is between smoking and lung cancer. Smokers are more likely to carry matches, and it is the smoking that is the true cause. The epidemiologic studies reviewed for this report all adjusted for potential confounding factors.

Effect modification: In some persons, an exposure increases risk of disease while in others it has no effect or has a smaller effect. This is called effect modification. An example is that obesity has a larger effect on risk for colon cancer in men than in women.

Generalizability: The goal for epidemiologic research is to identify causes of disease that can be applicable to all populations. Most modern-day case-control studies attempt to do this by conducting population-based studies. That is, they identify all cases of a cancer occurring in a population and attempt to interview as many of those cases as possible. They also identify a similar sample of persons from the same population who do not have cancer and attempt to interview as many of those as possible. Many of the case-control studies of talcum powder products identified cases through population-based cancer registries, which register almost 100% of cases of cancer occurring in the population served by the registry. These population-based studies are better able to produce results that are generalizable to the whole population. Hospital-based case-control studies of ovarian cancer include all cases of the cancer that present to a hospital and compare them to a comparable group of hospitalized patients without cancer. While the comparisons between cases and controls can be valid, the generalizability of the results to the population can be low if patients from the recruiting hospital differ from the population as a whole.

Generalizability can be more of an issue for cohort studies, depending on how the study participants were recruited. Three cohort studies have reported on talcum powder product use and ovarian cancer risk. The Women's Health Initiative recruited from the general population of postmenopausal women from 40 clinical centers around the U.S. The rate of response was only around 1-2%, however, and therefore the cohort is unlikely to represent the population of American postmenopausal women. The Nurses' Health Study recruited nurses from around the U.S. Their rate of response was higher than for the Women's Health Initiative, but they are all nurses, and therefore have different health knowledge, income, and socioeconomic status compared with the general U.S. population. The Sisters' Study recruited from the general population, targeting women who had at least one sister with breast cancer. The responding participants therefore represent only women with a family history of breast cancer, and given their self-selection, likely differ from the general population in vulnerability to cancer and other characteristics.

Exposure measurement: Defining whether a person is exposed to a potentially causal agent is critical to the science of epidemiology. For many exposures, we must rely on what the individual can tell us about their health habits, lifestyle, work history, and use of products and medications. Recall of these variables can be challenging. Epidemiologists, therefore, often have interviewers use tools to jog participants' memories, such as anchoring around particular ages and life events. The most thorough case-control studies queried about both frequency and duration of use of talcum powder products, as well as brand and type of product, and areas of exposure (e.g., perineal, sanitary napkin, other body areas, diaphragm, etc.) The ascertainment of use of talcum powder products is difficult, especially in determining dose of exposure, because women may have been using powders without being aware of what the product contained. Furthermore, information on the variable contents of talcum powder products (talc, fibrous talc, asbestos, other metals, fragrance) was not available to the scientists conducting the epidemiologic studies. While many epidemiologic case-control studies of talcum powder products and ovarian cancer risk asked women for brand names and dates of use, and analyzed data separately by likely powder contents, these analyses will not have been able to identify the various constituents of talcum powder products.

The Women's Health Initiative asked about duration of use of talcum powder products but did not ask about frequency of use.⁽²⁹⁾ The Nurses' Health Study asked about frequency of use but did not query regarding duration of use.⁽³¹⁾ The Sisters' Study asked participants about use of talcum powder

products in the 12 months before study enrollment, and the frequency of use.(30) None of the cohorts, therefore was able to estimate total lifetime dose of talcum powder product exposure. As described below, under-reporting of exposures will underestimate a true relative risk.(45) Therefore, the estimated relative risks in studies that looked at effects of talcum powder product use and risk of ovarian cancer may be under-estimates.

Diagnosis and classification of disease outcome: “Outcome” refer to the disease or health condition of interest; in this report, any type of epithelial ovarian cancer is the outcome. In some reports, cancers of the fallopian tubes and peritoneum are combined with epithelial ovarian cancer, as they are believed to be the same biological process and are treated the same as ovarian cancer with surgery and chemotherapy (<https://www.cancer.gov/types/ovarian/hp/ovarian-epithelial-treatment-pdq>).

Determination of outcomes (sometimes called “events”) is a critical part of epidemiologic research. If cases of a disease are over- or under-counted, results of exposure-disease associations will be skewed. If the source of cases differs from the source of controls, comparisons between cases and controls may be biased. In case-control studies, researchers try to include all cases that were newly diagnosed with the disease in a defined population within a set period. Population-based cancer studies often identify cases through population-based cancer registries. Hospital-based studies, conversely, identify cases that were newly diagnosed in one or more hospitals. Whichever method is used, researchers try to include and interview as high a proportion as possible of identified cases, to reduce chances of biased results.

For epidemiologic studies of cancer, it is important to identify, at the minimum, the type of cancer, stage of cancer at diagnosis, and subtype of cancer. Using pathologists’ reports from medical records, trained coders classify patients into the correct categories depending on the pathology and other medical records. There are several different subtypes of cancer of the ovary. Over 90% originate in epithelial tissues and are called “epithelial ovarian cancers.” The remaining 10% originate in other ovarian tissues (germ cell or sex-cord stromal). Of the epithelial ovarian cancers, approximately 70% are serous, 10% are endometrioid, 12% are clear cell, 3% are mucinous, 1% are Malignant Brenner, and the remaining are mixed histologies.(46) Epithelial ovarian cancer may be invasive or borderline. Only epithelial ovarian cancer has been studied in relation to use of talcum powder products. Therefore, in this report, “ovarian cancer” refers to “epithelial ovarian cancer.”

Types of Epidemiologic Studies on Ovarian Cancer and Exposure to Talcum Powder Products

Epidemiologists have assessed the relationships between use of talcum powder products and risk of ovarian cancer development, using several types of epidemiologic studies. The studies with the greatest number of cases of ovarian cancer used case-control designs. Most of these were designed specifically to address use of talcum powder products as a potential cause of ovarian cancer. Three cohort studies have also reported on associations between talcum powder product use and risk of ovarian cancer. These cohort studies were designed to test hypotheses relating hundreds of exposures to scores of disease outcomes including common cancers, cardiovascular disease, cerebrovascular disease, musculoskeletal diseases, and others. Finally, after several epidemiologic studies were published, researchers combined data from these studies using either meta-analyses or a pooled analysis. The pooled analysis also included data from previously unpublished studies, and therefore provide additional information beyond just summarizing results of published studies. All of these studies contribute to the science of the epidemiologic evidence relating use of talcum powder products to risk of ovarian cancer development. The totality of evidence on the causal effect of talcum powder product use on ovarian cancer development relies on data from epidemiologic studies, pathological evidence of migration to the ovaries of talc and other contents of talcum powder products (such as asbestos), and laboratory evidence.

Critical Components to Both Case-control and Cohort Studies

- 1) The accurate and complete ascertainment of cases. In case-control studies, this means that all cases of ovarian cancer should be identified in a given population and as high percent of them should be included in the study as possible. The controls should be free of ovarian cancer and should be as similar as possible to the cases except for the exposure under study. In cohort studies, this means that all individuals should be followed over time to determine how many did or did not develop ovarian cancer. For both types of studies, cases should be confirmed by medical record and pathological report review.
- 2) Precise determination of exposure. In both case-control and cohort studies, both cases and non-cases should have completed questionnaires about their current and past history of use of talcum powder products, including how often they used the products, when they began use, and number of years used.

In case-control studies, this is often done with the help of a trained interviewer. In cohort studies, which typically involve larger numbers of participants because only a small fraction will go on to develop specific diseases, questionnaires are usually self-administered without the assistance of an interviewer. In cohort studies, exposures should be updated after the baseline assessments, to ensure that changes in exposure can be captured. For an exposure like talcum powder product use, lifetime use would be relevant for determining total exposure. For both case-control and cohort studies, determining early life exposures depend on participants' ability to recall typical use patterns. Interviewer-administered surveys would typically include prompts to help participants recall past habits. Self-administered questionnaires may include some printed prompts, but these are usually minimal.

For a rare endpoint like ovarian cancer, a cohort must be followed for decades in order for a sufficient number of cases to accrue to determine effects of particular exposures. Therefore, there is the possibility of bias towards the null via changes in behavior over the course of the decades of follow-up. A woman who was originally classified as an "ever" talc user will remain an "ever" user even if she subsequently discontinued talc use. A "never" user who subsequently begins talc use will always be misclassified as a never user unless a follow-up survey records her change in status.

In ideal situations, the precise nature of the exposure would be verified. Despite habitual use, however, quantification of exposure is difficult.

(3) For both case-control and cohort studies, the populations should be well-characterized, so that any potential confounding variables can be accounted for in comparing exposure rates of cases and non-cases.

Case-control Studies

In case-control studies, individuals diagnosed with a specific type of cancer (cases) are compared with otherwise similar individuals who have not been diagnosed with cancer (controls). The control group is a sample of the population from which the cases arose and provides an estimate of how the exposures being studied are distributed in that population. In the ideal case, the controls will be similar to the cases on all variables other than the exposure under question. Therefore, epidemiologists often match

controls to cases on such variables as age, race, and ethnicity, or they include a large enough sample of participants that they can adjust for these variables.

Case-control studies can enroll a large number of cases, are usually less expensive than cohort studies, and can be completed over shorter periods of time. Relevant to this report, case-control studies also can be designed to answer specific questions related to one outcome, and participants can be queried in detail about certain exposures. Selection bias is an increasing problem if participation rates among case and control groups is substantially less than 100 percent, and where participation may be related (in different ways) to various exposures.

Case-control studies are subject to their own limitations, including recall bias, which can occur when participants' reports of various exposures are differentially affected by whether they are cases or controls in the study. This is a theoretical bias however; studies that have investigated other sources of data on exposures have failed to confirm the presence of differential recall between cases and controls.⁽⁴⁷⁾

One of the case-control studies of talcum powder product use and ovarian cancer risk (1) addressed this issue by counting as "users" only women who had used talcum powder products for at least six months, on at least a monthly basis. This procedure minimizes the potential over-reporting of minimal exposure by cases versus controls.

For this report, I reviewed 28 case-control studies, for most of which the association between use of talcum powder products and risk of ovarian cancer was a primary research questions.

Cohort Studies

In prospective cohort studies (usually called cohort studies), the exposures of a large group (cohort) of people who are assumed to be healthy are assessed, and the group is followed over a period of time. During the follow-up period, some members of the cohort will be diagnosed with cancer, while others will not, and comparisons are then made between these two groups. Cohort studies may need to be very large (up to hundreds of thousands of participants) to have sufficient statistical power to identify factors that may increase cancer risk by on the order of 20 or 30 percent. In addition, meaningful

comparisons between cases and non-cases can be made only for factors that vary sufficiently within the cohort. Importantly, cohort studies must identify exposures of interest when participants are enrolled into the study, in order to determine effect of the exposures on eventual development of the outcome of interest. Alternatively, if an exposure is ascertained some time after enrollment (as in the Nurses' Health Study ascertainment of talcum powder product use), the researchers will consider the date of collection of that exposure data to be the start date for follow-up of study participants. Because cohort studies typically are designed to look at multiple outcomes such as cancers, cardiovascular diseases, mortality, and other diseases, information collected on exposures tends to be minimal, to pertain to current levels of exposure, and may not be updated during follow-up.

Cohort studies provide the opportunity to obtain repeated assessments of participants' exposures at regular intervals, which may improve the assessment of the exposures. However, for this to happen, the investigators need to have planned for repeated measures of the exposure. In published cohort studies of talcum powder products and ovarian cancer risk, no repeated measures of talcum powder products were reported.

In cohort studies, the ascertainment and adjudication of cancer outcomes can be accomplished by directly asking participants about illnesses and hospitalizations, and requesting medical records for reviewing these events. In some cases, ascertainment of disease events may be accomplished by linking to a cancer registry.

For this report, I reviewed results of 3 cohort studies, published in 5 papers. None were designed specifically to look at the association between talcum powder product use and risk of ovarian cancer. Further, none of these studies fully ascertained exposure to talc, as will be discussed below.

Meta-analyses

Because there can be random variations within individual epidemiologic studies, and because very large sample sizes may be needed to see effects on rare diseases, epidemiologists rarely make causal inferences based on results of one study. Rather, we look at the totality of epidemiologic studies to determine patterns of exposure-disease relationships. Meta-analysis is a method used to combine the statistical results of several studies to produce an average estimate of effect of an exposure on an

outcome of interest. These summary estimates can provide evidence regarding the presence or absence of an association and can allow examination of dose-response relationships. In the area of talcum powder products use and ovarian cancer, 7 meta-analyses have been published (11, 22, 34-38), two of which are very recent and covered all studies contained in the previous meta-analyses.(34, 35) Of the 7 meta-analyses, 2 were included within reports of individual case-control studies (11, 22); the two recent meta-analyses contained all studies included in these 2 meta-analyses as well.

Pooled analysis is a type of meta-analysis where original individual-level data from various published and/or unpublished epidemiological studies are combined and re-analyzed. The combination of data from multiple studies creates a larger data set and increased statistical power. One such pooled analysis was published on the relationship between talcum powder product use and risk of ovarian cancer, and is heavily cited in this report because of its significance in including very high numbers of women with ovarian cancer and controls, thereby providing a high degree of statistical power.(39)

The 7 meta-analyses that I reviewed for this report included data from available cohort and case-control studies. I also reviewed the pooled analysis of 8 case-control studies.(39) In addition to effect measures (relative risks, odds ratios, hazard ratios) and their confidence intervals (or other test of statistical significance such as p-value), I reviewed the number of people with and without disease for each exposure category, method of exposure ascertainment, estimated exposure categories, assessment of dose-response effects, and effect sizes for all epithelial ovarian cancer and for subtypes of epithelial ovarian cancer (invasive, borderline, serous, endometrioid, mucinous, clear cell).

Possible Sources of Bias in Epidemiologic Studies Reviewed

All studies of all types must be critically evaluated for both strengths and potential limitations in order to determine the totality of evidence. Limitations in epidemiologic studies are often characterized as biases. These include the biases listed below. It is important to note that the presence of bias does not render an epidemiologic study invalid. Rather, biases are issues that should be carefully considered when assessing how much weight should be given to individual studies, and what conclusions can be drawn from them.

Missing data: Both case-control and cohort studies can suffer from missing data. If the missing data items are related to the use of talcum powder products, then the estimated relative risks/odds ratios will likely be artificially low. If, in cohort studies, the cases of ovarian cancer are not identified, i.e., the cancer data are missing, the statistical power to detect statistically significant effects will be lessened. Both of these conditions would likely mean the true association between use of talcum powder products and risk of ovarian cancer is actually higher than what is observed in the epidemiologic studies.

Poor precision of exposure measurement: Determining whether, how much, and for how long women were exposed to talcum powder products is difficult. Women may not remember the brand of powder products they used, and contents of personal powder products may not be clear or may change over time. Women may not remember the amount of products used, frequency of use, and years of use.

Publication bias: The publication of epidemiologic studies depends on several factors. The investigators must have developed hypotheses about certain questions and designed the study accordingly, including asking the correct questions about the exposure and potential confounding variables, and collecting information from a sufficient number of participants. The investigators then need to perform statistical analyses, develop scientific manuscripts, and submit for journal publication. It may be difficult to find a journal that will accept null results (i.e. where an exposure is shown to not be related to an outcome).(48, 49) The pooled analysis of case-control studies provides some reassurance that publication bias is less likely for this association.(39) Of the 8 studies included in that analysis, 3 had not been previously published. Ever use of talcum powder products in the genital area produced odds ratios of 1.37 (95% CI 1.07–1.67), 1.36 (95% CI (1.06–1.74), and 0.99 (95% CI 0.70–1.41) for the 3 individual studies. That the confidence intervals overlapped, and that 2 of the 3 studies showed statistically significant associations, suggest low publication bias for the association between use of talcum powder products in the genital area and risk of developing ovarian cancer.

Cancer process affecting likelihood of exposure: If women used talcum powder products in the perineal area due to symptoms from an early cancer process, results of studies could be biased. Cohort studies often guard against this by eliminating cases that develop within a short time of study enrollment. Case-control studies guard against this by asking participants to recall exposures one or more years prior to their cancer diagnosis (and similarly ask controls to recall exposures at least one year prior to interview).

Confounding: Variables related to both use of talcum powder products and risk of ovarian cancer could mask the true relationship between these variables. Epidemiologists handle this by adjusting in the analysis for these potential confounding variables. All of the studies reviewed performed adjustment for several potential confounding variables. Those studies that presented both adjusted and unadjusted odds ratios/relative risks found little effect of confounding variables on these relationships.

Recall bias: For the case-control studies, media reports of associations between talc and ovarian cancer could have influenced cases such that they recalled use of talcum powder products to a greater degree than controls. However, the studies for which data collection pre-dated news reports of this association showed similar effects to those for which data were collected afterward. Thus, “recall bias” is unlikely to be an issue. As mentioned above, recall bias is a theoretical bias; studies that have investigated other sources of data on exposures have failed to confirm the presence of differential recall between cases and controls.(47)

Non-response bias: Case-control studies with low levels of response in cases or controls can be biased, in that the non-responding cases and controls could differ with respect to use of talcum powder products.

Differential results of cohort versus case-control studies: Ideally, results of case-control and cohort studies would be similar for the relationship between an exposure and risk of disease. However, there could be several reasons for discrepancy in results between case-control and cohort studies. The exposure measurement may differ in the two types of studies. For example, cohort studies may measure exposure at study entry without updating and without ascertaining lifetime exposure. The study would then have only one time point of an exposure that could significantly attenuate the observed associations between exposure and disease.

Population-based case-control versus hospital-based case-control studies: For some exposure-disease relationships, population-based case control studies are the most valid method of comparing risk for exposed versus non-exposed persons because the risks to public health can better be estimated. For others, however, hospital-based case control studies may provide important information because controls with illnesses may be more likely to recall exposures compared with healthy controls from the community, and therefore recall bias can be reduced.

Causal Inference in Epidemiology

The overarching goal of epidemiologic research is to determine likely causes of disease, in order to determine who is at risk for that disease and how to prevent the disease in individuals and populations. Much of epidemiologic observational research in cancer focuses on determining the *associations* between an exposure and an outcome. In other words, in a sample of individuals, are the number of persons exposed to an agent more likely to develop a cancer than those who are not exposed? There are several related questions. For example, will the persons who are exposed to a higher dose have an even greater risk than persons with little exposure? Will those exposed for a longer period of time have greater risk than those exposed for only a short time? Epidemiologists follow guidelines and logic in determining likelihood of an exposure causing cancer.(50) In addition to epidemiologic data, epidemiologists also consider plausible biological mechanisms to explain observed associations. The weight of evidence depends on the validity of the data as well as the clinical and biological evidence, if available, to explain these associations.

In epidemiology, and therefore in this report, a positive association means that the exposure in question increases risk for a disease or outcome. A negative association refers to an exposure decreasing risk for the outcome.

In 1965, English epidemiologist Sir Austin Bradford Hill attempted to describe several aspects of the causal relationship in a speech to the Royal Society of Medicine's newly-established Section of Occupational Medicine.(43) As Bradford Hill explained, this is not a checklist of factors to be counted: "What I do not believe—and this has been suggested—is that we can usefully lay down some hard-and-fast rules of evidence that must be obeyed before we accept cause and effect. None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine qua non*."

These aspects of a causal relationship are:

Strength of the association. If the risk of developing cancer is several times higher in persons exposed to a toxic agent, that increases the likelihood of causality. It is not a necessary condition for establishing causality and providing recommendations for avoiding a potential cancer-causing agent, however.

Indeed, several carcinogens raise risk of cancer less than doubling of risk, but because of a high prevalence of exposure, can have major public health effects. Other exposures may be highly prevalent to certain groups such as factory workers; such exposures need to be minimized to meet government regulations for worker safety. Several examples follow:

Alcohol and risk for postmenopausal breast cancer: Risk for postmenopausal breast cancer increases by approximately 10% (a relative risk of 1.1) for each 10 gram/day intake of alcohol (the amount in a four-ounce glass of wine).(51) Women are advised to avoid alcohol or minimize alcohol intake to no more than one alcoholic drink per day to reduce risk for this cancer.(51) As Bradford Hill pointed out in his address: "We must not be too ready to dismiss a cause-and-effect hypothesis merely on the grounds that the observed association appears to be slight. There are many occasions in medicine when this is in truth so."(43)

Air pollution and risk for cardiovascular disease: A 2013 meta-analysis found that for each 10 $\mu\text{g}/\text{m}^3$ rise in $\text{PM}_{2.5}$, the air pollution caused by motor vehicles, yields an 15% increase in risk of cardiovascular disease (similar to a relative risk of 1.15). Given the widespread prevalence of exposure to ambient pollution, even modest contributions to cardiovascular disease risk can have a substantial effect on population health. (52)

Outdoor particulate matter air pollution and lung cancer: A 2014 meta-analysis including 18 studies showed a relative risk of 1.09 (95% CI 1.04-1.14) per 10- $\mu\text{g}/\text{m}^3$ of exposure to particulate matter ($\text{PM}_{2.5}$).(53) This is highly significant, because 10- $\mu\text{g}/\text{m}^3$ of exposure to $\text{PM}_{2.5}$ is the lowest recommended limit set by IARC for minimizing health effects of air pollution.

Benzene at work and risk of leukemia: In 2010, a meta-analysis of 15 epidemiologic studies found that worksite benzene exposure increased risk of any leukemia by 40% (relative risk 1.40, 95% CI 1.23-1.57).(54)

Estrogen-progestin menopausal hormone therapy and breast cancer risk: The Women's Health Initiative clinical trial showed that this type of hormone therapy increases risk of breast cancer by 26% after an average 5 years of use. That level of risk was sufficient for clinical interest groups and governmental agencies to advise women to use hormone therapy for limited periods of time, if at all, because of risk

for breast cancer and other adverse events with similar levels of increased risk (29% increase in coronary heart disease, and 41% increase in stroke).(55) A meta-analysis of clinical trials and observational studies in 2018 found that use of this therapy increased risk of breast cancer by 59% (relative risk 1.59, 95% CI 1.40-1.81).(56) These results led to FDA-required label warnings on estrogen and progesterone therapy preparations(57), and to clinical warnings against use of estrogen plus progesterone for prevention of chronic conditions.(58)

Trichloroethylene and risk of kidney cancer: In 2012, a meta-analysis was published showing that occupational exposure to trichloroethylene was associated with an approximately 30% increased risk for kidney cancer (relative risk 1.32, 95% CI 1.17-1.50).(59)

Regular physical activity is associated with reduced risk for cardiovascular disease, diabetes, and various cancers in persons who meet national physical activity guidelines of 150 minutes/week of moderate-intensity aerobic activity.(60) In one large pooled analysis of 6 cohorts with 661,137 men and women, investigators found a 20% lower mortality risk among those performing less than the recommended minimum of 7.5 metabolic-equivalent hours per week (hazard ratio, 0.80 [95% CI, 0.78-0.82]), a 31% lower risk at 1 to 2 times the recommended minimum (hazard ratio, 0.69 [95% CI, 0.67-0.70]), and a 37% lower risk at 2 to 3 times the minimum (hazard ratio, 0.63 [95% CI, 0.62-0.65]).(61) To compare with the relative risks for adverse exposure, one would look at the inverse of the hazard ratios, i.e., 1.25, 1.45, and 1.59.

Intermittent intense sun exposure and risk of melanoma: A 2005 meta-analysis included data from 57 epidemiologic studies with 38,671 cases of melanoma, and found a relative risk of 1.61 (95% CI 1.31-1.99) for intermittent intense sun exposure.(62)

Prevention of skin cancer with use of sunscreen has also been observed, with similar effect sizes. In a 4.5-year trial with an additional 8-years follow-up, individuals randomly assigned to daily sunscreen use had almost a 40% reduced risk of squamous cell carcinoma (rate ratio, 0.62; 95% confidence interval, 0.38-0.99).(63) To compare with the relative risks for adverse exposure, one would look at the inverse of the risk ratio, i.e., 1.6.

Consistency of the association. A consistent association would be observed in various populations, places, circumstances, and times. Has the association been found in different countries, in persons from

various race/ethnic groups, and of different ages? This is also not a requirement, as there could be occasions when an exposure only increases risk for specific categories of individuals. An example, again from the breast cancer field, is that obesity increases risk for breast cancer occurring after menopause but decreases it for women who have not yet undergone menopause. Relevant to the association between ovarian cancer risk and use of talcum powder products, the association has been observed in the U.S., Canada, China, Australia, Israel, and the UK. While most data have been collected in Whites, a positive association between use of talcum powder products and risk for ovarian cancer has also been found in Blacks and Asians.

Specificity of the association: This suggests that if an exposure causes only one type of disease, that its causal link to that disease is strengthened. However, Bradford Hill recognized the limits of this aspect. One noxious agent, such as tobacco smoke, is an accepted cause of multiple cancers as well as cardiovascular disease. Similarly, one disease can have multiple causes. For example, lung cancer risk is increased with exposure to radon and asbestos, even in persons who do not smoke. In support of this, Bradford Hill stated, “One-to-one relationships are not frequent. Indeed I believe that multi-causation is generally more likely than single causation...”(43)

Temporality: The time course between exposure and disease occurrence is an important consideration. Bradford Hill was referring to the need to document that the exposure came before the disease, rather than something about the disease causing a person to come into contact with the exposure. This is why, for case-control studies, researchers have often queried women about their lifetime history of use of talcum powder products, beginning from young ages. Some cohort studies, on the other hand, asked about current use of these products when the women were first enrolled in the cohort. However, for all of these studies, only talcum powder product use prior to the cases’ diagnoses (and prior to a comparable time point for controls, in case-control studies) was counted as “exposure.”

Biologic gradient: This refers to the dose-response curve or the shape of the association between exposure and risk as the amount of exposure changes. If risk for a disease increases with increasing amount of exposure, the likelihood of a causal relationship is often increased. The exposure can be classified by total duration of exposure, by usual amount of exposure, or by a combination of these two. For use of talcum powder products, dose has been estimated by total years of use, by frequency of use, and by a combination of these two variables. It should be noted that ovarian talc particle burden may

not be influenced by number of applications of perineal talc usage(64), and therefore the typical dose-response relationship may not be necessary for establishing causality between perineal talcum powder product use and risk for ovarian cancer. Indeed, there are numerous substances for which there is no safe dose.

Plausibility: The association is strengthened if it is biologically plausible. However, Bradford Hill recognized that “What is biologically plausible depends upon the biological knowledge of the day.” It is important to note that biologic plausibility does not require proof of mechanism.

Coherence: The cause-and-effect interpretation of the data should not significantly conflict with the known facts about the natural history and biology of the disease. Therefore, for example, the concurrent rise in tobacco smoking rates and rise in lung cancer incidence in the 20th century in the U.S., as well as the more recent concurrent decrease in smoking rates and decrease in lung cancer occurrence, strengthen the association between smoking and lung cancer as causal. For the case of use of talcum powder products and ovarian cancer risk, the prevalence of other risk and protective factors (e.g., use of oral contraceptives, hysterectomy, and tubal ligation as protective factors, obesity as risk factor) changed over time in the general population. Therefore, it would be difficult to determine if ovarian cancer incidence time trends vary by changes in use of talcum powder products. The biology involves, as described below, the migration of talc to the ovaries, the inflammatory process which talc elicits, and the carcinogenetic effects of inflammation.

Experiment: The evidence from randomized controlled trials can provide strong support to observational evidence. However, in many situations, randomized controlled trials are not feasible. In the case of talcum powder products and ovarian cancer risk, a trial would have to be very large, involving 50,000 women or more, followed for decades, to determine effects of use of talcum powder products on risk for ovarian cancer. This is because ovarian cancer is a rare disease and typically takes many years to develop to be clinically diagnosable. In addition, because the effects of genital talcum powder product use could be harmful, it would be unethical to conduct a trial of this type.

Analogy: Bradford Hill states that in some circumstances it would be fair to judge by analogy. Therefore, since some toxic agents such as thalidomide or rubella have been shown to cause birth defects, other drugs or viral exposures may be recognizable as possibly leading to harmful effects to a

fetus. Regarding talcum powder products use and ovarian cancer use: since increased inflammation has been associated with increased ovarian cancer risk, and since talc causes an inflammatory response in tissues, this strengthens the link between talcum powder products use and ovarian cancer risk.

Methods Used for this Review

In performing this evidence review and for purposes of my opinions, I first conducted a review of the relevant literature on the epidemiology of ovarian cancer risk in relation to use of talcum powder products, using the same process I use for systematic review articles I write for my academic work.(60, 65) I triaged articles by title, then by abstract, and finally by complete paper. As I read the epidemiologic literature, I considered the “Bradford Hill” aspects of causal inference(43), as well as causal inference as defined by Rothman(50), and weighed the evidence. My search identified studies that both support and do not support my eventual opinion on whether use of talcum powder products can cause ovarian cancer.

I searched in the PubMed database for research studies published in peer-reviewed, PubMed indexed journals, using the following search terms: (“talc” OR “talcum powder”) AND (“ovarian cancer” OR “ovarian carcinoma”).

The search produced 110 references, of which 7 included meta-analyses (11, 22, 34-38), one was a pooled analysis (39), and 33 were reports of original epidemiologic studies that tested the association between talcum powder products and risk of ovarian cancer.

I did not perform a meta-analysis, because excellent meta-analyses have been recently published,(34, 35) and all of the published meta-analyses showed similar relative risk estimates for use of talcum powder products and risk of ovarian cancer. For all of the reviewed studies, I performed data extraction using a standardized data extraction table (see Tables 1-4). I recorded information on the publication year, study design, number of cases, number of controls (for case-control studies), total sample size (for cohort studies), population type, country, risk estimates, confidence intervals, and the type of ovarian cancer. I also indicated whether dose-response relationships were assessed, method used, and results.

In this report, I provide descriptions of the study methods and main study results including risk estimates (odds ratio, relative risk, or hazard ratio). All studies included control for some confounders and presented the risk estimates with adjustment for the confounders. I present below the results from adjustment with the greatest number of variables.

Epidemiologic Evidence on the Association between Talcum Powder Products Use and Ovarian Cancer Risk

Case-control Studies

Schildkraut *et al.* (2016)(1) investigated the association between body powder use and ovarian cancer in African American women in 11 geographic areas of the U.S. Included were 584 cases and 745 controls, in a population-based study. Cases were identified through state or SEER cancer registries, or through hospital gynecologic oncology departments. Controls were randomly selected from the same populations as the cases. Participants were asked in a phone interview whether they had ever regularly used talc, cornstarch, baby, or deodorizing powders. Women were classified as “regular users” if they reported using any of these powders at least monthly for at least 6 months, and “never users” otherwise. Regular users were asked about frequency and duration of use; use on genital areas, underwear, sanitary napkins, or diaphragms; and use on non-genital areas. Lifetime number of applications was estimated as number of applications per month times number of months used. Occupational exposure (yes/no) was ascertained for a subset of participants. Use of genital powder was associated with a statistically significant 44% increased risk for ovarian cancer (odds ratio 1.44, 95% CI 1.11-1.86). A dose-response trend was noted: compared with never-users, women who used genital powder less than daily had a 12% increased risk for ovarian cancer, while women who used genital powder daily had a 71% increased risk. The statistical test for trend was significant ($p < 0.01$). Furthermore, a greater number of years used increased risk further: compared with never-users, women who used genital powders for less than 20 years had a 33% increased risk of ovarian cancer, while those who used genital powders for 20 years or more had a 52% increased risk of ovarian cancer. The statistical test for trend was significant ($p = 0.02$). Estimated lifetime number of applications was also related to risk in a dose-dependent manner. Compared with never users, those who used fewer than 3600 genital powder applications had a 16% increased risk for ovarian cancer, while those who used 3600 or

more applications had a 67% increased risk. The statistical test for trend was significant ($p < 0.01$). Risk of both serous and non-serous ovarian cancer increased statistically significantly with any genital powder use by 38% and 63%, respectively (odds ratios, 1.38, 95% CI 1.03-1.85, and 1.63, 95% CI 1.04-2.55, respectively).

Cramer *et al.* (2016) (2) reported on association between genital talc use and risk of ovarian cancer in 2,041 cases of ovarian cancer and 2100 controls. Cases were combined from three case-control studies interviewed in 1992-97, 1998-2002, and 2003-2008. Cases were identified from tumor boards and registries in Eastern Massachusetts and Massachusetts. Controls were identified from the same populations as controls. Interviewers asked participants if they “regularly” or “at least monthly” applied powder to the genital or rectal area, sanitary napkins or tampons, underwear, or non-genital areas. Type of powder, age begun, years used, and applications per month were ascertained. Lifetime exposure was estimated by multiplying frequency of applications per month by months used, and talc-years were calculated. Participants were then divided into quartiles according to these variables. Participants were also asked if their partners dusted or sprayed powder to their genital or rectal areas. Condom and diaphragm use were ascertained as potential sources of genital talc exposure. Genital talc use was associated with a statistically significant 33% increased risk of ovarian cancer (odds ratio 1.33, 95%CI 1.16-1.52). Risk decreased with increasing time since last use. There was a clear trend to increasing risk for ovarian cancer with increasing frequency of use: compared with never users, risks for 1-7 days per month, 8-29 days per month, and 30 or more days per month were increased by 17%, 37%, and 46%, respectively, and the trend was statistically significant ($p < 0.0001$). Furthermore, as months per year of use increased, risk increased, and the trend was statistically significant ($p = 0.006$). Risk for serous invasive, endometrioid invasive, and serous borderline were increased with any genital talc use, by approximately 40%, and all were statistically significant. Risks of serous invasive and endometrioid also increased significantly with increased talc-years of use. Risks of serous invasive were increased in both premenopausal and postmenopausal women who used genital products, but the results were only statistically significant in premenopausal women. Premenopausal women and postmenopausal women using hormone therapy had the largest risks associated with talcum powder product use for most types of ovarian cancers.

Wu *et al.* (2015) (3) investigated the associations of risk of ovarian cancer and talcum powder products use and other risk factors. Cases were identified through the SEER population-based University of

Southern California cancer registry. A total of 1,701 patients were included; and 2,319 controls were recruited from the cases' neighborhoods using random selection from population lists. In-person interviews were conducted. To determine use of talcum powder products, women were asked if they ever used talc at least once per month for 6 months or more.⁽⁶⁾ If the response was positive, they were asked whether they had ever used talc in non-perineal areas (feet, arms, chest or back), perineal areas, or on underwear or sanitary pads/diaphragm. Questions on talc use included age at first use, frequency of use (times per month) and years of talc use. Use of genital talc for one year or more was associated with a statistically significant 46% increased risk for ovarian cancer (odds ratio 1.46, 95% CI 1.27-1.69). Similar relative risks were seen in non-Hispanic white, Hispanic, and African-American women. A dose-response analysis found that for each 5-year use of genital talc products, risk for ovarian cancer increased by a statistically significant 14% (95% CI 1.09-1.20).

Kurta *et al.* (2012)⁽⁴⁾ published results of a population-based case-control study based in Western Pennsylvania, Eastern Ohio, and Western New York State. A total of 902 cases were enrolled, and 1,802 controls were randomly selected from the general population of those areas. Perineal talc use was defined as ever using dusting powder or deodorizing spray on the genital or rectal areas, on sanitary napkins, on underwear, or on diaphragms or cervical caps. Use of perineal talc increased risk for ovarian cancer by a statistically significant 40% (odds ratio 1.40, 95% CI 1.16–1.69).

Rosenblatt *et al.* (2011) ⁽⁵⁾ published results of a population case-control study set in western Washington that investigated the association between genital powder exposure and risk of ovarian cancer. A total of 812 women with ovarian cancer were identified through a population-based cancer registry and interviewed. A total of 1,313 controls were selected at random from the western Washington population. Sources of genital powder were ascertained, including direct perineal application, use on sanitary napkins and diaphragms, and use of deodorant vaginal spray. For powder use on sanitary napkins and use of vaginal deodorant sprays, the authors recorded the total number of months or years in which these products were used. For use of perineal powder, the investigators recorded the age began and ended, number of weeks or months of use per year, and average days per week used. Study participants were also asked about the types of powder used, including talcum, baby, cornstarch, deodorant, body/bath, and other or unknown. The authors then calculated the lifetime duration of use, and estimated lifetime number of applications. Perineal use of powder was associated with a non-statistically significant 27% increased risk for ovarian cancer (odds ratio 1.27, 95% CI 0.97-

1.66). The risk for borderline ovarian tumors was statistically significantly raised by 55% (odds ratio, 1.55, 95% CI 1.02-2.37), whereas risk for invasive ovarian cancers was increased by a non-statistically significant 27% (odds ratio 1.27, 95% CI 0.87-1.58). Use of powder on either sanitary napkins or diaphragms did not increase risk. Use of vaginal deodorant spray increased risk by a non-statistically significant 15% (odds ratio 1.15, 95% CI 0.85-1.56). None of the dose-response or time variables (years of use, lifetime number of applications, age at first use, age at last use, calendar year of first use, time since first and last uses) showed evidence of increasing relative risk of ovarian cancer with increasing level of exposure to talcum powder products. Similarly, there was no evidence of increased risk for ovarian cancer with increasing dose of powder use on sanitary napkins, or of vaginal deodorant sprays. Use of perineal powder increased risk for mucinous borderline, serous borderline, endometrioid, and other non-mucinous ovarian cancers by 47% to 78%, but none of the odds ratios was statistically significant.

Wu *et al.* (2009) (6) presented results of a case-control study of ovarian cancer with 609 cases and 688 controls. Risk of ovarian cancer among users of talcum powder products in the perineal area was increased by 53% (odds ratio 1.53, 95% CI 1.13-2.09). Risk of serous ovarian cancer was also significantly elevated (odds ratio 1.70, 95% CI 1.27-2.28). A statistically significant trend to increased risk with lifetime numbers of applications was observed. Compared with no use, odds ratios for those with ≤ 5200 , $>5200 - \leq 15,600$, $>15,600 - \leq 52,000$, and $> 52,000$ applications were 1.2, 1.38, 1.34, and 1.99, respectively ($p_{\text{trend}} = 0.0004$).

Moorman *et al.* (2009) (7) published data from a population-based case-control study in White and Black women. In total, 1114 cases and 1086 controls were interviewed. They found no association of genital talcum powder product use and risk for ovarian cancer in Whites (odds ratio 1.04, 95% CI 0.82-1.33), and a non-statistically significant increased risk in Blacks (odds ratio 1.19, 95% CI 0.68-2.09). Neither dose-response nor effects by histologic subtype were addressed.

Merritt *et al.* (2008) (8) published results from an Australian-wide population-based case-control study on talcum powder products and risk of ovarian cancer. Included were 1,576 women with ovarian cancer and 1,509 population-based controls. Women provided information on self-administered questionnaires. They were asked if they had ever used powder or talc in the genital area, on underwear, or on sanitary pads or diaphragms. They were also asked about age at first use and years of talc use in

these areas. Duration of talcum powder use prior to and after surgical sterilization was calculated, and all analyses were limited to the time when the fallopian tubes would have been patent. Use of talc elsewhere was also collected. Ever use of talc in the perineal region was associated with a statistically significant 17% increased risk for ovarian cancer (odds ratio 1.17, 95% 1.01-1.36). The increase was strongest for serous (odds ratio 1.21, 95% CI 1.03-1.44), but was also seen for endometrioid (odds ratio 1.18, 95% CI 0.81-1.70). A statistically significant dose-response trend for years of perineal talcum powder use prior to surgical sterilization was seen for all cases combined ($p=0.021$) and for serous ovarian cancer ($p=0.022$). While not statistically significant, increasing years of use was associated with increased risk of mucinous and endometrioid ovarian cancers.

Mills *et al.* (2004) (9) reported on a population-based case-control study in 22 counties of Central California. A total of 256 cases were recruited from cancer registries and interviewed, and 1,122 population-based controls were randomly selected and interviewed. Women were asked the following about use of talcum powder: use in the genital area, years of use, frequency of use, and total duration of use. Ever use of perineal talc statistically significantly increased risk for ovarian cancer by 37% (odds ratio 1.37, 95% CI 1.02-1.85). There was a statistically significant trend found in the dose-response analysis of frequency of use; women using talc 4-7 times per week had a 74% increased risk for ovarian cancer ($p=0.015$). There was an indication of trend with duration of use up to 4-12 years, although number of years beyond that did not increase risk further. A similar relationship was found for cumulative dose (frequency times duration). Risk of serous ovarian cancer was also statistically significantly elevated (odds ratio 1.77, 95% CI 1.12-2.81).

Ness *et al.* (2000) (10) recruited women with ovarian cancer ascertained from 39 hospitals in Eastern Pennsylvania, Southern New Jersey, and Delaware. A total of 767 cases of ovarian cancer were interviewed, along with 1,367 population-based controls. Women were asked if they ever used talc, baby, or deodorizing powder at least once per month for 6 or more months in their genital or rectal area, on sanitary napkins, on underwear, on a diaphragm or cervical cap, or on non-genital areas. They also were asked about male partner use of talc to the genital area or underwear. Compared with never-users, women who used talc in genital/rectal areas had a statistically significant 50% increased risk for ovarian cancer (odds ratio 1.5, 95% CI 1.1-2.0). Those who used it on sanitary napkins had a statistically significant 60% increased risk for ovarian cancer (odds ratio 1.6, 95% CI 1.1-2.3). Use on underwear increased risk by a statistically significant 70% (odds ratio 1.7, 95% CI 1.2-2.4). Use on a

diaphragm/cervical cap or by a male partner did not increase risk. Among those who used in the genital/rectal or other body areas, there was no evidence of increasing risk with increasing numbers of years of use.

Cramer *et al.* (1999) (11) published results of a population-based case-control study with 563 cases of ovarian cancer and 523 controls. Risk of ovarian cancer among women with perineal talcum powder product exposure was increased 60% compared with non-exposed (odds ratio 1.6, 95% CI 1.18-2.15). Risk of invasive serous ovarian cancer was significantly increased (odds ratio 1.7, 95% CI 1.22-2.39). No dose-response effect, as defined by duration, was seen.

Wong *et al.* (1999)(12) conducted a hospital-based case-control study in Buffalo, NY, comparing 499 patients with ovarian cancer and 755 patients with non-gynecological malignancies. No details were given on how talcum powder product use was ascertained, but women were queried on site of talc use (sanitary napkin vs. genital/thigh area) and duration of use. Compared with non-users, those who used on sanitary napkins or genital/thigh areas had no increase in risk for ovarian cancer. Furthermore, there was no apparent trend toward greater risk with longer duration of use. Finally, there was a non-statistically significant 20% increased risk of serous ovarian cancer with talcum powder product use (odds ratio 1.2, 95% CI 0.7-2.1).

Godard *et al.* (1998)(13) studied risk of sporadic (101 cases) or familial (51 cases) ovarian cancer according to perineal talc use compared with 152 control in Montreal, Canada. Cases were diagnosed at one of two teaching hospitals; controls were randomly selected from the population. Talc use questions were not detailed in the paper, but the variable of “ever” versus “never” perineal use of talc was reported. Women who had ever used perineal talc had a 2.49 times greater risk of developing any ovarian cancer (relative risk 2.49, 95% CI 0.94-6.58, $p=.066$), which was marginally statistically significant. The relative risk for sporadic ovarian cancer was 2.45 (95% CI 0.85-7.07, $p=0.098$), and for familial ovarian cancer it was 3.25 (95% CI 0.85-12.4, $p=.084$).

Green *et al.* (1997)(14) included 824 Australian women with ovarian cancer who were identified through cancer registries, as well as 855 population-based controls. No details were provided on the specific questions posed regarding talc use, but perineal use was ascertained, as well as duration and ages/years used. Women who had ever used talc in the perineal region had a statistically significant 30% increased

risk for ovarian cancer (relative risk 1.3, 95% CI 1.1-1.6). The authors investigated whether a history of surgical sterilization affected this relative risk (the rationale being that women who are surgically sterilized would have lower chance of talc migrating up to the ovaries). They found that compared with women who had neither used talc nor had surgical sterilization, risk was highest among talc users without surgery (relative risk 1.3, 95% CI 1.0-1.7) and lowest among women with a history of tubal sterilization or hysterectomy who had not applied talc to the perineum (relative risk 0.6, 95% CI 0.5-0.84). No dose-response relationship by duration of use was found.

Cook *et al.* (1997) (15) reported on a population-based case-control study including 313 cases of ovarian cancer identified through a cancer registry and 422 population-based controls in Western Washington. Women were queried about storing diaphragms in powder, dusting perineal areas with powder after bathing, powdering sanitary napkins, and using genital deodorant sprays (which may contain aerosolized powder). Women were further asked about duration and frequency of powder application and about types of powder applied. There was a statistically significant 50% increase in risk of ovarian cancer associated with use of any of the genital powder applications (perineal application, sanitary napkins, genital deodorant sprays, diaphragms) (relative risk 1.5, 95% CI 1.1-2.0). The risk was highest, and statistically significant, in those women who dusted perineal areas with powder (relative risk 1.8, 95% CI 1.2-2.9). Compared with never users of genital deodorant sprays, women who used these products for 12 months or less had a relative risk for ovarian cancer of 1.5, while those who used them for more than 12 months had a relative risk of 2.7. Compared with never users of genital deodorant sprays, women who used 500 lifetime applications or less of genital deodorant sprays had a relative risk for ovarian cancer of 1.7, while those who used more than 500 applications had a relative risk of 2.6. Both of these dose-response trends were statistically significant ($p < 0.05$). None of the other types of perineal talcum powder product use showed trends to greater risk with greater estimated duration used or applications. The authors then categorized powders into specific types: cornstarch, talcum powder, baby powder, deodorant powder, and scented body/bath powder (assuming talcum powder was likely a constituent of the latter three as well). Exclusive use of cornstarch, or of deodorizing powder, was not associated with increased risk for ovarian cancer, but the numbers of cases were very small (5 and 9, respectively). Exclusive use of other types of powder increased risk between 20 and 60 percent, but the results were not statistically significant. Risk for serous ovarian cancers was statistically significantly increased by 70% in women who ever used any genital powder (relative risk 1.7, 95% CI 1.1-2.5). The relative risk for

“other tumors” among ever users was 1.8 (95% CI 1.1-2.8), while risks for mucinous or endometrioid tumors were not increased in genital powder users.

Chang *et al.* (1997)(16) reported on the association between talcum powder product use and risk of ovarian cancer in a population-based case-control study in Ontario, Canada. A total of 450 patients with borderline or invasive ovarian cancer and 564 population controls were interviewed. Women were asked about regular talc use and type of talc used, as well about duration and frequency of use. Women were queried about regular application of talc to the perineum and about use of talc on sanitary napkins. Use of cornstarch on the perineum and sanitary napkins was also ascertained. Women with any regular talc exposure had a statistically significant 42% increased risk of developing ovarian cancer (odds ratio 1.42, 95% CI 1.08-1.86). Use of cornstarch was not associated with increased risk, although this was a very uncommon exposure in this study. Use of talc on sanitary napkins increased risk to a lesser degree (odds ratio 1.26, 95% CI 0.81-1.96), as did use of talc only in the perineal area (odds ratio 1.31, 95% CI 1.00-1.73). A dose-response trend was seen: per 10 years of use of talc to the perineal area, risk of ovarian cancer increased by 6% (odds ratio 1.06, 95% CI 0.99-1.14). Frequency of use per month, however, did not show a dose-response trend. Use before and after 1970 showed almost identical odds ratios. Risk was higher prior to tubal ligation/hysterectomy than after either procedure. Risk was increased for all types of ovarian cancer included (invasive, borderline, serous, mucinous, and endometrioid). Only for invasive cancer was the odds ratio statistically significant, likely due to the larger numbers of cases in that category.

Shushan *et al.* (1996)(17) published results of a population-based case-control study in Israel, looking at the association between talcum powder product use and risk of invasive or borderline ovarian cancer. A total of 200 cases, identified through a cancer registry, were interviewed, as were 408 controls selected randomly from the same population. Details of the talcum powder product use on the standardized questionnaire were not provided. Women who reported using talc “moderate to a lot” versus “never or seldom” had twice the risk of developing ovarian cancer, and the result was statistically significant (odds ratio 2.0, $p=0.04$).

Purdie *et al.* (1995)(19) studied the association between talcum powder product use and ovarian cancer risk in 3 Australian states. Cases were recruited from registries at three oncology treatment centers, and controls were chosen randomly from the general population. The details of the interview items on talc

were not provided. Women who used talc around the perineum or abdomen had a statistically significant 27% increased risk for ovarian cancer (odds ratio 1.27, 95% CI 1.04-1.54).

Cramer *et al.* (1995)(18) published results of two case-control studies, in which a total of 450 women diagnosed with ovarian cancer in Boston, MA area hospitals, and 454 controls selected from the general population, were interviewed. Use of talc “in genital hygiene” was associated with a 60% increased risk for ovarian cancer (odds ratio 1.6, 95% CI 1.2-2.1).

Tzonou *et al.* (1993)(28) conducted a hospital-based case-control study in Athens, which included 189 women with ovarian cancer and 200 hospital visitor controls. No information was provided on how talcum powder product use was ascertained, other than that women were interviewed about whether or not they used of talc in the perineal area. There was little evidence of an association: the relative risk for ovarian cancer in those who said “yes” versus “no” to perineal talc use was 1.05 (95% CI 0.28-3.98). However, only 6 cases and 7 controls reported using talc in the perineal area.

Rosenblatt *et al.* (1992)(20) published results of a hospital-based case-control from the Baltimore, MD area. A total of 77 cases of ovarian cancer and 46 controls, who were treated for non-gynecologic/non-malignant diseases, were included. Participants were interviewed about presence and length of genital fiber and respiratory fiber exposure. Fiber exposure was defined as exposure to asbestos, talc, and fiberglass. Dose of exposure was calculated as number of years of each type of genital or respiratory exposures from all sources, and only exposure prior to tubal ligation (for women who had that procedure) was counted. Use of genital talc was associated with a 70% increased risk (odds ratio 1.7, 95% CI 0.7-3.9). Use of talc on sanitary napkins resulted in almost a 5-fold statistically significant increase in risk of ovarian cancer (odds ratio 4.8, 95% CI 1.3-17.8). Talc use on diaphragms tripled risk for ovarian cancer (odds ratio 3.0, 95% CI 0.8-10.8). The odds ratios for these latter two exposures were not statistically significant. Women who had exposure years above the median had more than double the risk of ovarian cancer compared with women with lower exposure years (odds ratio 2.4, 95% CI 1.0-5.8).

Chen *et al.* (1992)(21) interviewed 112 women with ovarian cancer and 224 community controls in China. No information was provided about how women were asked about talcum powder product use prior to 3 years before diagnosis (for cases) and a comparable date in controls. Seven cases and 5

controls reported using “dusting powder” to the lower abdomen and perineum for 3 or more months, giving a relative risk of 3.9 (95% CI 0.9-10.6).

Harlow *et al.* (1992) (22) published a case-control study with 235 cases of ovarian cancer and 239 controls. The authors found a 50% increased risk of ovarian cancer in women who had ever versus never used talcum powder products in the perineal area with marginal statistical significance (odds ratio 1.5, 95% CI 1.00-2.1). Risk of serous cancer was similarly increased (odds ratio 1.4, 95% CI 0.9-2.2). Risk by number of lifetime applications indicated a dose response effect. Compared with no use, odds ratios for those with < 1000, 1000 – 10,000, and > 10,000 were 1.3, 1.5, and 1.8, respectively ($p_{\text{trend}} = 0.09$).

Booth *et al.* (1989) (23) reported on a hospital-based case-control study conducted in 15 hospitals in the UK. A total of 235 cases with ovarian cancer and 451 controls were interviewed and asked about monthly experiences from age 16 to 45 years. Frequency of exposure to perineal talc was ascertained. Compared with never-users, women who used genital talc rarely, monthly, weekly, and daily, respectively, had relative risks for ovarian cancer of 0.9, 0.7, 2.0, and 1.3, respectively, and the trend was statistically significant ($p=0.05$). Cases and controls did not differ by percentage who stored diaphragms in talc.

Harlow *et al.* (1989)(24) interviewed 116 women with serous or mucinous borderline ovarian cancer identified through a Western Washington population-based cancer registry, as well a population-based sample of 158 control women. The authors used an open-ended question asking women to specify the types of powder they used for perineal application after bathing, on sanitary napkins, and on diaphragms. Powder was categorized as baby, deodorizing, other/unspecified talcum, or cornstarch. There was no association between perineal use in general and risk for borderline ovarian cancer, but women who reported using powder on sanitary napkins had a relative risk of 2.2 (95% CI 0.8-19.8) compared with nonusers. Women who used deodorizing powders had a statistically significant relative risk of 2.8 (95%CI 1.1-11.7). No data were presented on frequency or duration of use.

Whittemore *et al.* (1988)(25) included 188 ovarian cancer cases (identified through 7 hospitals in the San Francisco, CA area, and 539 controls (of which approximately half were hospital controls and half were population-based controls). Women were asked whether they had ever use talcum powder on the perineum, on sanitary pads, or on diaphragms, and about frequency and duration of use. Women who

reported using talcum powder to the perineum had a non-statistically significant 45% increased risk for ovarian cancer (relative risk 1.45, 95% CI 0.81-2.60). Use on sanitary pads was associated with a non-statistically significant 38% reduced risk, and use on diaphragms was associated with a non-statistically significant 50% increased risk. The relative risk for ovarian cancer increased with increasing applications of talc per month; relative to nonusers, the relative risk for 1-20 times per month was 1.27, and the relative risk for 20 or more times per month was 1.45. None of these values was statistically significant. The increased relative risk was apparent for women who had never had tubal ligation or hysterectomy, but not for women who had had one of these procedures. Compared with non-users, women with 1-9 years of use had a relative risk of 1.6 (95% CI 1.00-2.57), but women with greater years of use had only a relative risk of 1.11 (95% CI 0.74-1.65).

Hartge *et al.* (1983)(26) provided a brief report on a small hospital based case-control study of ovarian cancer, which included 135 cases and 171 controls from the Washington, DC area. No information was provided on how the talc exposure was ascertained. The authors found that women who reported genital talc use had a relative risk of 2.5 compared with never users (95% CI 0.70-10.0), but this analysis was based on only 7 cases and 3 controls.

Cramer *et al.* (1982) (27) published the first study to look at the association between talcum powder product use and risk of ovarian cancer. This population-based study found an odds ratio of 1.92 (95% CI 1.27-2.89) for ever use of perineal talcum powder products in the perineal area. Dose-response was not addressed.

Summary of Case-control Studies

These 28 case-control studies included population-based and hospital-based studies from a diverse geographic area across the U.S., as well as Australia, Canada, the UK, Israel, Greece, and China. Sample sizes ranged from 77 to 2041 cases, with comparable numbers of controls. Of the 28 studies, 24 found odds ratio greater than 1.1 for ovarian cancer in women who had any perineal exposure to talcum powder products, compared with never users(1-6, 8-11, 13-23, 25-27). Of these 24 odds ratio estimates, 16 were statistically significant (95% confidence intervals excluded 1.0 or p value ≤ 0.05)(1-4, 6, 8-11, 14-19, 27). Among the 8 studies which were not statistically significant, 7 had a sample size lower than that estimated to be needed to have power to detect a statistically significant result(13, 20-23, 25, 26). It is

important to note that while the 8 studies did not have statistically significant results, they provide relevant data because their relative risk estimates were consistent with the 16 studies that showed statistically significant results.(50)

Both population-based and hospital-based studies were represented in the literature on use of talcum powder products and risk of ovarian cancer, and odds ratios/relative risks were similar across the two classes of studies. Earlier studies were less likely to address dose-response relationships, or to investigate effects of talcum powder product use on specific histologic subtypes of ovarian cancer. Most studies were limited to white women; later studies included larger numbers of Black women as well as Asian and Latina women.

The larger, and more recent studies, however, added important information on dose-response relationships and on risk of particular histologic subtypes of ovarian cancer. Many of the 28 studies found evidence of a dose-response effect(1-3, 6, 8, 11, 20, 22, 23, 25). Most often, this took the form of lifetime numbers of applications of talcum powder products or years of use. The later studies determined that some risk of some subtypes, particularly serous ovarian cancer, were more highly related to use of talcum powder products.

Taken together, the case-control studies, conducted over 40 years, provide consistent and replicated evidence of increased risk of ovarian cancer with perineal exposure to talcum powder products, with evidence of a dose-response. They support the conclusion that talcum powder products can cause ovarian cancer.

Prospective Cohort Studies

The Sisters' Study

The Sisters' Study cohort analysis included 135 cases of women with ovarian cancer, 7 cases of fallopian tube cancer, 4 cases of peritoneal cancer, and 8 cases with unknown primary site. (30) Of the total 154 cases, only 96 were confirmed by medical records or death certificate. Women were recruited to the cohort from across the United States from 2003-2009. An analysis of talcum powder products use and ovarian cancer risk, published in 2016, included 41,654 women who reported having at least one ovary

and no history of ovarian cancer at study entry, from among 50,884 women aged 35-74 years at study enrollment with at least one sister who had been diagnosed with breast cancer.

Talcum powder products use for the 12 months prior to study entry was ascertained by self-administered questionnaires. Questions included frequency of genital talcum powder products use in the form of powder or spray applied to a sanitary napkin, underwear, diaphragm, cervical cap, or vaginal area. Response categories were: did not use, used less than once a month, used 1-3 times/month, used 1-5 times/week, or used more than 5 times/week. Only a dichotomous variable—use/nonuse—was used in the analysis. Ovarian cancer cases were identified by yearly follow-up questionnaires; no updates on talc use were included. The median follow-up of study participants was only 6.6 years.

Contrary to all of the other epidemiologic studies, perineal talc use was associated with a non-statistically significant 27% decreased risk of developing ovarian cancer (hazard ratio 0.73, 95% CI 0.44 - 1.2). Of note, the 95% CI's included 1.2, so the true relative risk in this cohort could have been in the range of the other studies. Use of talcum powder products during ages 10-13 years showed a non-statistically significant 10% increase in risk (hazard ratio 1.1, 95% CI 0.74, 1.7). No data on risk by ovarian cancer subtype were presented.

Women's Health Initiative

In 2014, a report on the use of perineal powder in relation to ovarian cancer risk was published, using a total of 429 cases of women with ovarian cancer from the Women's Health Initiative cohort study.⁽²⁹⁾ Women were aged 50-79 years at study entry, and were recruited from 40 clinical centers across the United States between 1993-1998. While over 93,000 women were enrolled in the Women's Health Initiative cohort, this analysis included only 61,576. The largest number, 20,960, were excluded because they reported previously having had both ovaries removed or did not know whether they had any ovaries at the time of enrollment. Also excluded were 10,622 women with a history of any invasive cancer at enrollment. A further 516 were missing follow-up information. At study entry, women reported use of perineal powder on self-administered standardized questionnaires, in which they were asked if they had ever used powder on their genital areas. Those who responded yes were then asked to indicate if they used them for less than 1 year, 1-4 years, 5-9 years, or 20 or more years. Women who reported ever using a diaphragm were asked if they used powder on the diaphragm, and for what

duration. Women were also asked if they used powder on a sanitary napkin/pad, again with questions about duration. Because of the relatively small number of ovarian cancer cases (429) that occurred during the study, the investigators combined the duration categories into never, 9 years or less, or 10 years or more. The investigators then created one variable by combining the perineal use, diaphragm use, and sanitary napkin use, with duration as the maximum duration for any of the 3 application areas. Cases of ovarian cancer were identified by participants on annual follow-up questionnaires; no updates on talc use were included. Medical records and pathology reports were requested for each self-reported case and were adjudicated by clinic physicians and central cancer adjudicators. A total of 429 cases were included in the analysis.

Ever use of perineal powder was associated with a non-statistically significant 6% increased risk of ovarian cancer compared with never use (hazard ratio 1.06, 95% confidence interval 0.87 - 1.28). Risk of serous invasive cancer was increased by a non-statistically significant 13% (hazard ratio 1.13, 95% CI 0.84 - 1.51). Both of these results, while not statistically significant, are consistent with an association between talcum powder product use and risk of ovarian cancer overall and of serous ovarian cancer.

Nurses' Health Study

The Nurses' Health Study is a cohort established in 1976 that had 307 cases of ovarian cancer at its initial publication in 2000; further data with a total of 210 cases were published in 2008; and an unknown number of cases were analyzed for publication in 2010. The study initially enrolled 121,700 registered nurses between the ages of 30-55 years from across the United States. Use of talcum powder was ascertained on the self-administered 1982 questionnaire only, by asking women if they had ever commonly used talcum, baby powder, or deodorizing powder on their perineal areas. Possible responses were: no, daily, 1-6 times per week, or less than once per week. Women were also asked if they had applied these products to sanitary napkins. "Ever talc use" was classified as ever talc use on either the perineal area or sanitary napkins. Every two years, participants reported health updates; no updates on talc use were included, but self-reported cases of ovarian cancer were adjudicated through medical record reviews. Women were excluded from talcum powder products analyses if they did not complete the information on the 1982 questionnaire, if they reported having had both ovaries removed, if they had had a hysterectomy but did not report whether or not they had at least one ovary remaining, or if they had a history of radiation therapy.

There have been three publications from the Nurses' Health Study on the relationship between talcum powder products and risk for ovarian cancer.(31-33) The first, published in 2000, included 78,630 women, of whom 307 cases of ovarian cancer were diagnosed during a 14 year follow-up period. Ever use of talc was reported by 40.4% of the cohort; 14.5% ever used talc daily.(31)

The risk of ovarian cancer was not statistically significantly associated with epithelial ovarian cancer overall (relative risk 1.09, 95% CI 0.86-1.37), and risk did not increase with increasing frequency of use. Risk of serous ovarian cancer, however, was statistically significantly increased by 40% in women who had ever used talc (relative risk 1.4, 95% CI 1.02-1.91).

The second report from the Nurses' Health Study was in 2008.(32) In this study, 210 cases and a random sample of 600 controls from the Nurses' Health Study were combined with cases and controls from other case-control studies. Among the Nurses' Health Study cases and controls, the relative risk for ovarian cancer was 1.24 (95% CI 0.83-1.83).

Daily use was associated with a 44% increase in risk (relative risk 1.44, 95% CI 0.88-2.37), although neither association was statistically significant. Given that only 210 Nurses' Health Study cases were included, the lack of statistical significance is likely due to this insufficient sample size.

The third Nurses' Health Study report was published in 2010.(33) This report looked at multiple menstrual, hormonal, health habits, and familial risk factors for ovarian cancer; the variable on use of talc to the perineal area was limited to a dichotomous "greater than or equal to once per week vs. less than once per week".

Use of talc one or more times per week compared with less use was not statistically significantly related to risk for epithelial ovarian cancer (relative risk 1.06, 95% CI 0.89-1.28), serous invasive (relative risk 1.06, 95% CI 0.84-1.35), or for other subtypes including endometrioid, or mucinous ovarian cancer.

It is difficult to compare the results of these three Nurses' Health Study publications. The first and third used different categories of use as the referent (comparison) group. The first publication used "never use" as the comparison and found a statistically significant effect for risk of serous ovarian cancer with

any use of talcum powder products. The third publication combined “never use” and “less than once per week” into one referent category. If low frequency use increases risk of ovarian cancer, which is entirely plausible, combining such women with never users will seriously underestimate the true relative risk associated with use of talcum powder products. The second publication found increased risks of total and serous ovarian cancer with use of talcum powder products, but the numbers were small and therefore the results were not statistically significant.

Cohort Studies Analysis

Two of the three cohort studies found small increases in risk of ovarian cancer overall among women who used talcum powder products in the perineal areas. The results were not statistically significant for ovarian cancer overall, however, likely due to insufficient sample size or incomplete ascertainment of talc exposure. The first Nurses’ Health Study publication found a statistically significant association between ever versus never use and risk of serous ovarian cancer. The Sisters’ Study found a reduced risk of ovarian cancer but did not report data by histologic subtype of ovarian cancer. Similar to the Nurses’ Health Study, the Women’s Health Initiative found an increase, albeit non-statistically significant, in risk of serous ovarian cancer in users versus nonusers of talcum powder products.

There were serious limitations to these cohort study analyses. None of the studies were specifically designed to investigate the relationship of talcum powder product use and risk of ovarian cancer. Rather, the cohorts were designed to study a large number of outcomes and a wide variety of exposures. Thus, none of the studies obtained detailed lifetime histories of talcum powder product use, although two did ask about duration of use for current users. None, therefore, was able to accurately measure dose of exposure. The sample sizes (numbers of cases) of most of the cohort study publications were likely too small to be able to detect a relative risk in the order of 1.24 (the value found in the Terry pooled analysis(39)) with reasonable power, especially for different histologic subtypes.

To assess likelihood of inadequate sample sizes in these cohort studies, I used an online calculator: <http://www.openepi.com/SampleSize/SSCohort.htm>. I used WHI data(29) to estimate the cohort sizes needed to determine a true relative risk of 1.24 (i.e. the relative risk from Terry et al pooled analysis(39)) with 50% exposure to talcum powder products in non-cases, and an assumption of 0.5% occurrence of ovarian cancer in unexposed women(66) over 12 years’ follow-up (the mean number of years of follow-

up in the WHI publication). My calculations show that to have sufficient power to identify a statistically significant relative risk of 1.24, the necessary cohort size would be over 140,000. None of the 3 cohorts had this large a sample size for these publications. Sample size ultimately rests on the numbers of cases that occur, rather than the actual cohort size. While the third Nurses' Health Study publication(33)—had a large sample size of cases, the authors' choice to combine never users with less than once per week users could have significantly attenuated the relative risk estimates.

Results of the cohort studies were overall attenuated compared with results of the case-control studies. However, the trend for 2 of the 3 studies was a positive relative risk of talcum powder product use and risk of ovarian cancer. In the Nurses' Health Study, women who used these products had a statistically significant 40% increased risk of developing serous invasive ovarian cancer compared with non-users.(31) In that study, use in the perineal area directly or on sanitary napkins increased risk of ovarian cancer overall by a non-statistically significant 15%.

In the Women's Health Initiative, use of talcum powder products to the genital area (or on sanitary napkins or diaphragm) increased risk overall by a non-statistically significant 6%, and risk of serous invasive ovarian cancer by a non-statistically significant 13%.

The Sisters Study asked only about use of talcum powder product use in the 12 months prior to enrollment; just 14% of the cohort used these products in that period. The cohort included only women at high risk for breast cancer recruited beginning in 2003—this may have been a group of women who were aware of the potential carcinogenic effect of talc, and therefore avoided use. This cohort study found a non-statistically significant 27% lower risk of developing ovarian cancer in users versus non-users. Given the likely 30-50-year latency of ovarian cancer development after exposure to a carcinogen(67), however, these results of the Sisters' Study are not likely reflective of risk from exposure to talcum powder products.

It is important to note that the effect sizes in the Nurses' study and in the Women's Health Initiative were in the same direction as seen in virtually all of the case-control studies.

Therefore, the attenuated results from these cohort studies do not reduce my confidence in the observations from the 28 case-control studies described above.

In summary, while the cohort studies on average showed more attenuated relative risks of ovarian cancer in relation to use of talcum powder product use, their results as a group do not negate the significant case-control study findings and the significant results of the meta-analyses and the pooled analysis.

Meta-Analyses and Pooled Analyses

I reviewed 7 meta-analyses (11, 22, 34-38) and one pooled analysis (39). All of the meta-analyses, and the pooled analysis, found summary elevated risks for ovarian cancer associated with use of talcum powder products. These elevated relative risks were statistically significant. Although many of the source studies from which they performed their meta-analyses had elevated risks for ovarian cancer with use of talcum powder products, the relative risks or odds ratios were not all statistically significant. I interpret the lack of statistical significance in some source studies as being due to the small sample sizes of many of these studies. I calculated the sample size required for a study in which 40% of controls used talcum powder products, in which there is good power (80%) to detect a relative risk of 1.3, and that had low chance of estimated a particular relative risk by chance (<http://www.openepi.com/SampleSize/SSCC.htm>). The calculation showed that the minimum number of cases and controls would need to be 931 each, for a total sample size of 1862. Almost none of the case-control or cohort studies had sample sizes this large. Lack of statistical significance found in the various studies is likely due to their small sample sizes. For this reason, evaluation of the meta-analyses and pooled analysis, with their larger sample sizes, is critical to understanding the state of epidemiologic evidence linking use of talcum powder products to risk of ovarian cancer.

Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-analysis (R. Penninkilampi, Eslick GD, 2018)

In this, most recent, meta-analysis and systematic review, the authors searched 6 electronic databases, and selected observational studies with at least 50 cases of ovarian cancer.(34) They analyzed the association between ovarian cancer, including specific sub-types, and the following variables regarding talcum powder products: any perineal talc use, long-term (> 10 years) use, total lifetime applications, and use on diaphragms or sanitary napkins. Included were 24 case-control studies, with 13,421 ovarian

cancer cases. Also included were three cohort studies, with 890 cases and a comparison of 181,860 person-years [numbers of non-cases multiplied by the years of follow-up]).

The authors found that any perineal talc use was associated with a statistically significant 31% increased risk for ovarian cancer (odds ratio 1.31, 95% CI 1.24-1.39).

There was evidence of a dose-response effect by number of lifetime applications. Women whose lifetime applications totaled less than 3600 had a statistically significant 32% increased risk of developing ovarian cancer (odds ratio 1.32, 95% CI 1.15-1.50), while those whose lifetime applications totaled over 3600 had a statistically significant 42% increased risk for ovarian cancer (odds ratio 1.42, 95% CI 1.25-1.61).

Increased risks were seen for all types of ovarian cancer, as well as specific subtypes: all serous (odds ratio 1.32, 95% CI 1.22-1.43), serous invasive (odds ratio 1.32, 95% CI 1.13-1.54), serous borderline (odds ratio 1.39, 95% CI 1.09-1.78), and endometrioid (odds ratio 1.35, 95% CI 1.14-1.6). For all of these subtypes, the confidence intervals did not include 1.0, and therefore are considered statistically significant and unlikely to be due to chance findings. For other subtypes, the following non-statistically significant associations were seen: all mucinous (odds ratio 1.12), mucinous invasive (odds ratio 1.34), mucinous borderline (odds ratio 1.18), and clear cell (odds ratio 1.02).

The association between ever use of talc and overall ovarian cancer risk was higher in case-control studies (odds ratio 1.35, 95% CI 1.27-1.43) than in cohort studies (odds ratio 1.06, 95% CI 0.90-1.25). However, the results for case-control and cohort studies were similar for serous ovarian cancer. In cohort studies, risk for serous invasive cancer was statistically significantly increased by 25% with any perineal talc use (odds ratio 1.25, 95% CI 1.01-1.55), and in case-control studies, it was statistically significantly increased by 36% (odds ratio 1.05-1.75). There was insufficient information from the cohort studies to calculate the dose-response variable (total lifetime applications).

In my opinion, the results of this 2018 meta-analysis give strong support for an association between perineal talcum powder product use and risk for ovarian cancer. A significant number of the aspects of the causal relationship that Bradford Hill describes in his address are present in these data, including strength, consistency, temporality, and biologic gradient. Bradford Hill did not define his first aspect—

strength—other than to say that the likelihood of causality is greater if the agent causes a “several fold higher” increase in risk in exposed persons. However, for agents like perineal talcum powder products that have such high prevalence of use (over 50% in some populations), the odds ratio/relative risk/hazard ratio for perineal talc use is of great importance for both public health and clinical medicine because it means that perineal talc use causes a significant number of ovarian cancer cases every year.

The corollary example of combined estrogen plus progesterone menopausal hormone therapy and breast cancer risk is helpful here. The Women’s Health Initiative clinical trial showed that this type of hormone therapy increases risk of breast cancer by 26% after an average 5 years of use. That level of risk was sufficient for clinical interest groups and governmental agencies to advise women to use hormone therapy for limited periods of time, if at all, because of risk for breast cancer and other adverse events with similar levels of increased risk (29% increase in coronary heart disease, and 41% increase in stroke).(55) Further examples of relative risks less than 1.5 that have significant public health impact because of high prevalence of exposure in the population or in specific subgroups are shown on pages 26-27.

Genital Use of Talc and Risk of Ovarian Cancer: A Meta-Analysis (Berge W, Mundt K, Luu H, Boffetta P, 2017)

The authors of this meta-analysis performed a systematic search of PubMed, Embase, and Scopus databases(35). After quality assurance and redundancy checks, they included in their analysis 24 case-control studies and 3 cohort studies that reported on the association between talcum powder products and risk of developing ovarian cancer. The main meta-analysis compared ever versus never use of genital talc. Additional analyses looked at use of powder on sanitary napkins and diaphragms. Stratified analyses were conducted for tumor types.

From the meta-analysis, the authors observed a statistically significant 22% increased risk of developing ovarian cancer in women who had ever used genital talc versus never users (relative risk 1.22, 95% CI 1.13-1.30).

Significant results were found for dose-response relationships, both for number of years of use and for number of applications. Each 10-year increase in genital talc use was associated with a 16% increase in

risk for developing ovarian cancer (relative risk 1.16, 95% CI 1.07-1.26). Furthermore, each increase of one application per week was associated with a 5% increase in risk (relative risk 1.05, 95% CI 1.04-1.07).

Risk of serous carcinoma was the only subtype of ovarian cancer for which risk was elevated, and it was statistically significant (relative risk 1.24, 95% CI 1.15-1.34). “Late” exposure, which the authors hypothesized could be less likely to include asbestos, conferred a higher risk (relative risk 1.31, 95% CI 1.03-1.61) than did “early” exposure (relative risk 1.18, 95% 0.99-1.37). Neither specific use on a sanitary napkin nor on a diaphragm increased risk. Ever use of genital talc on a diaphragm was associated with decreased risk (relative risk 0.75, 95% CI 0.63-0.88).

The association of talcum powder use with increased risk of ovarian cancer was seen in case-control studies (relative risk 1.26, 95% confidence interval 1.17-1.35) but not in cohort studies (relative risk 1.02, 95% confidence interval 0.85-1.2). Furthermore, hospital-based case-control studies had a higher summary relative risk compared with population-based case-control studies (relative risks 1.34 and 1.24, respectively, both statistically significant).

In my opinion, the results of this meta-analysis are very similar to those of the later one described above, and further support the causal effect on ovarian cancer of talcum powder products applied in the perineal area.

Perineal Use of Talc and Risk of Ovarian Cancer (Langseth, Hankinson, Siemiatycki, Weiderpass, 2017)

In a meta-analysis conducted by some of the researchers who had investigated the epidemiologic research on talc exposure and ovarian cancer risk for IARC, data from 20 case-control studies were combined into a meta-analysis.⁽³⁶⁾ The authors found an overall odds ratio of 1.35 (95% CI 1.26-1.46) for ever- versus never-use of talcum powder products. The authors did not perform dose-response analyses.

Perineal Application of Cosmetic Talc and Risk of Invasive Epithelial Ovarian Cancer: A Meta-analysis of 11,933 Subjects from Sixteen Observational Studies. (Huncharek, Geschwind, Kupelnick, 2003)

This meta-analysis included fifteen case-control and two cohort studies that had been published between 1966 and early 2001, and that fit eligibility criteria, including documenting type of talc exposure (e.g. dusting perineum vs. sanitary napkins). The meta-analysis produced a statistically significant relative risk of 1.33 (95% confidence intervals 1.16-1.45) for ever versus never use of talc in the perineal area.(37)

The investigators addressed dose-response in the seven studies with information on years of talc exposure or numbers of talc applications per month. However, the authors combined categories of dose (applications per month) and duration of use (years) into one variable, and treated the dose-response analysis as if dose and duration were measuring the same construct. Their statement of lack of dose-response effect, therefore, is misleading in my opinion. The authors suggest that perhaps talc use has a similar carcinogenic effect as asbestos, and cites research showing that asbestos does not show a clear dose-response effect on risk of mesothelioma.

The authors also separated the results of hospital-based (e.g. both cases and controls from the same hospitals) from non-hospital-based (controls selected from the general population) and found a lower relative risk for ovarian cancer (1.19, not statistically significant) for the hospital-based studies and 1.38 (statistically significant) for population-based studies. The authors state that the hospital-based studies would be more accurate because they eliminate bias from case referral patterns to particular hospitals. However, many of the non-hospital-based studies used population-based case ascertainment (e.g. cancer registries) and selected population-based controls, which also eliminates the potential bias of hospital referral patterns.

Genital Talc Exposure and Risk of Ovarian Cancer (Cramer, Liberman, Titus-Ernstoff, Welch, Greenberg, Baron, Harlow, 1999)

In a paper that presented data for a case-control study of genital talc exposure and risk of ovarian cancer, Cramer et al. presented results of a meta-analysis of previous publications on the relationship between talcum powder product use and risk of ovarian cancer.(11) The authors included results from

14 case-control studies, from which they found a statistically significant combined odds ratio of 1.36 (95% confidence interval 1.24-1.49).

A Meta-Analytical Approach Examining the Potential Relationship between Talc Exposure and Ovarian Cancer (Gross and Berg, 1995)

In a meta-analysis sponsored by the Johnson and Johnson company, Gross and Berg included nine case-control and one cohort study in a meta-analysis, and found that the relative risk for women “exposed” versus “non-exposed” to talc was a statistically significant 1.27 (95% confidence interval 1.09-1.48).(38) Eliminating studies that included non-epithelial ovarian tumors, and studies that did not adjust for potential confounders, the relative risk remained statistically significant (relative risk 1.29, 95% confidence interval 1.02-1.63).

Perineal Exposure to Talc and Ovarian Cancer Risk (Harlow, Cramer, Bell, Welch, 1992)

Harlow and colleagues presented results of a meta-analysis of previous publications on the relationship between talcum powder product use and risk of ovarian cancer (in the same paper in which they presented data on a case-control study of ovarian cancer risk in relation to perineal talcum powder product exposure).(22) The authors included results from 6 case-control studies, from which they found a statistically significant combined odds ratio of 1.3 (95% confidence interval 1.1-1.6).

Genital Powder Use and Risk of Ovarian Cancer: A Pooled Analysis of 8,525 Cases and 9,859 Controls (Terry KL *et al.*, 2013)

This pooled analysis used resources and data from the Ovarian Cancer Association Consortium, including 8 population-based case-control studies with relevant data on talcum powder product use.(39) Six of the studies were conducted in the U.S.(5, 7, 11, 68-70), one in Australia(8), and one in Canada(16). The analysis included 8,525 cases of ovarian, fallopian tube, or peritoneal cancer and 9,859 controls selected from the general population. Five of the studies had previously reported on use of talcum powder product and risk for ovarian cancer (5, 7, 8, 11, 16). To harmonize data on genital powder use across the studies, Terry *et al.* defined genital powder use as any type of powder (talc, baby, deodorizing,

cornstarch, or unspecified/unknown) applied directly or indirectly (by application to sanitary pads, tampons, or underwear) to the genital, perineal, or rectal area. Study-specific powder questions varied in detail about type and method of application. However, the authors were able to classify women into those who “ever used” genital powders vs. those who “never used” powders in the genital area. The included studies also had extensive data on other suspected risk factors for ovarian cancer that were adjusted for in the analyses. To measure cumulative dose of genital powder use, the authors estimated lifetime number of powder applications by multiplying total months of use by frequency of use per month.

Genital powder use was reported by 25% of controls and 31% of cases. In the pooled analysis, ever use of genital powder was associated with a statistically significant 24% increased risk of ovarian cancer (odds ratio 1.24, 95% CI 1.15-1.33) versus women who never used these products. In contrast, women who had used powders only in non-genital areas had no increase in risk for ovarian cancer. Risk for several subtypes of ovarian cancer was statistically significantly increased in women who had used genital powders. Risk for invasive serous cancer was increased by 24% (1,952 cases; odds ratio 1.24, 95% CI 1.13-1.35). Risk for endometrioid cancer was increased by 20% (568 cases; odds ratio 1.2, 95% CI 1.03-1.4), and risk for clear cell cancer was increased by 26% (327 cases; odds ratio 1.26, 95% CI 1.04-1.52). Risk of serous borderline cancer was increased by 45% (odds ratio 1.45, 95% CI 1.24-1.69). Risk of mucinous cell invasive cancer and mucinous cell borderline cancer were not statistically significantly associated with use of genital powder products (206 cases; odds ratios 1.06, 95% CI 0.82-1.26; and 409 cases; 1.19, 95% CI 0.98-1.43, respectively).

There was a striking similarity in findings across studies, and the statistical test for heterogeneity was not significant ($p > 0.61$). All but one study showed odds ratios greater than 1.0, of which 5 were statistically significant (i.e., the confidence intervals did not contain 1.0).

To assess dose-response effects, the authors categorized participants who had used genital powder into 4 equal groups by lowest to highest level of use (quartiles), and compared their risk for ovarian cancer to that in non-users. A clear dose-response trend was evident. Compared with never users of genital powder, women in quartile 1 had a 14% increased risk for ovarian cancer (odds ratio 1.14, 95% CI 1.00-1.31), women in quartile 2 had a 23% increased risk for ovarian cancer (odds ratio 1.23, 95% CI 1.08-1.41), women in quartile 3 had a 22% increased risk for ovarian cancer (odds ratio 1.22, 95% CI 1.07-

1.40), and women in quartile 4 had a 32% increased risk for ovarian cancer (odds ratio 1.32, 95% CI 1.16-1.52). Slightly higher odds ratios were seen when the cancers were restricted to non-mucinous subtypes (i.e., serous invasive, endometrioid invasive, clear cell invasive, and serous invasive): 1.18, 1.22, 1.22, and 1.37, respectively, for increasing levels of use by quartiles. When all 5 categories were included, the trend was highly statistically significant ($p_{\text{trend}} < 0.0001$).

The authors performed some additional analyses to make sure that the results were not biased. First, they excluded cases and controls who only began to use genital powders after undergoing tubal ligation or hysterectomy (after which powder likely would not migrate to the ovaries). This had no effect on the odds ratios—the increased risks for ovarian cancer remained virtually identical in each quartile. They then looked at effect of genital powder use and ovarian cancer risk by subgroups of women according to other ovarian cancer risk factors. They found no significant interactions between genital powder use and parity, reported history of endometriosis, tubal ligation/hysterectomy, or menopausal status. They did find that the effect of genital powder use was higher in normal/overweight women (odds ratio 1.28, 95% CI 1.17-1.39) than it was in women with obesity (odds ratio 1.14, 95% CI 0.98-1.32).

Finally, the authors looked at associations between genital powder use and ovarian cancer by years of beginning use. They found that the association between genital powder use and ovarian cancer risk was similar for women who started use between 1952 and 1961 (odds ratio 1.36, 95% CI 1.19–1.56), between 1962 and 1972 (odds ratio 1.27, 95% CI 1.11–1.46), and after 1972 (odds ratio 1.31 95% CI 1.15–1.51). However, they observed an attenuated association for women who started genital powder use before 1952 (odds ratio 1.08, 95% CI 0.93–1.25).

The Terry *et al.* pooled analysis provides strong evidence that perineal talcum powder product use causes ovarian cancer. “Strong” here does not pertain to size of the odds ratio/relative risk. Rather, it refers to the fact that the number of cases included was larger than any previous study, the 8 case-control studies included showed similar effect sizes for association of genital powder use and ovarian cancer risk (consistency), the dose-response effect was clear, and there were enough numbers of cases to determine effects on subtypes of ovarian cancer.

Summary of Meta-analyses/Pooled Analysis Results

All of the meta-analyses and the pooled analysis demonstrate increased risk of ovarian cancer in women who used talcum powder products in the genital or perineal area compared with nonusers. The earlier meta-analyses included fewer studies, primarily case-control studies. The most recent meta-analyses included three cohort studies and 24 case-control studies.(34, 35) The summary relative risks were quite consistent across the meta-analyses and the pooled analysis, ranging from 1.22 to 1.4 for any versus no use of perineal talcum powder products. Furthermore, all of the summary results were statistically significant. Importantly, the later meta-analyses(34, 35) and the pooled analysis(39) assessed dose-response relationships, while earlier meta-analyses did not(11, 22, 36), or did so inaccurately(37). These findings of increased risk of ovarian cancer with perineal exposure to talcum powder products shows that the observed associations overall and those for dose-response are robust.

One striking observation across the meta-analyses and pooled analysis is that the total sample sizes (numbers of cases) in all of the meta-analyses and the pooled analysis were sufficient to detect statistically significant relative risks of 1.3 for an overall “exposed” versus “non-exposed” variable with prevalence of 40 percent (see page 48 for a calculation of needed sample size). As shown in Tables 3 and 4, the numbers of cases in the meta-analyses and pooled analysis ranged from 1106 to 14,311, with controls of equal or greater number. All of these, therefore exceed the sample size I estimated that is needed to have statistical power to determine relative risks of 1.3. In contrast, many of the individual case-control or cohort studies did not have large enough samples of cases to have statistical power to determine a relative risk of 1.3.

Asbestos, Fibrous Talc, and Heavy Metals in Talcum Powder Products

It is important to note that talc is not asbestos-free. Talcum powder products contain other, potentially carcinogenic substances; of greatest concern is the presence of asbestos in talc, and the presence of talc with asbestiform fibers (fibrous talc), in these products. The presence of any one of these constituents add to evidence of biologic plausibility that would support the consistent increased risk seen in the epidemiologic studies.

Asbestos can take several forms. Proven carcinogenic forms include serpentine (chrysotile) and amphibole (actinolite, amosite, anthophyllite, crocidolite, and tremolite) minerals.(40) Both serpentine and amphibole asbestos forms are classified by IARC as Class 1 carcinogens(40). In their 2012 report, IARC stated that talc deposits may include tremolite, anthophyllite, and actinolite forms of asbestos(40).

Talc may form true mineral fibers that are asbestiform in habit. This form of talc is also referred to as fibrous talc and classified by IARC as a Class 1 human carcinogen(40). The IARC report also noted that “talc containing asbestiform fibers” is not the same as “talc contaminated by asbestos”(40). The conclusions reached in the 100c monograph about asbestos apply to fibrous talc (40). IARC has classified platy (non-fibrous) talc as a 2B “possible” carcinogen(42).

The primary route of exposure to asbestos is respiratory in the general population, although exposure through drinking water and exposure to hair or clothing of asbestos workers has also occurred (40). For talc, the primary exposures listed by the IARC report are respiratory and perineal (40).

Asbestos has been established as a cause of several types of cancer including epithelial ovarian cancer (40, 41). In order to assess the causal relationship between asbestos and ovarian cancer, I conducted a literature search. My search yielded a total of 26 studies that have investigated the epidemiology of asbestos exposure and risk of ovarian cancer. Two of these were meta-analyses, both published in 2011.(71, 72) One was a pooled analysis of 43 Italian cohorts with high asbestos exposure. (73) In addition, IARC published monographs on the carcinogenic role of asbestos, and conducted a systematic review through 2009 of asbestos and risk of ovarian cancer. (40, 41, 74) IARC concluded that asbestos, fibrous talc, chromium, and nickel are Group 1 human carcinogens.(40) IARC also classified cobalt as a 2B “possible” carcinogen.

Published data as recently as 2014 have shown that present-day talcum powder products include several types of asbestos.(75, 76) Company documents and testimony also provide further evidence of the presence of asbestos, fibrous talc, and heavy metals in talcum powder products.(77, 78) Dr. William Longo tested historical samples provided in litigation. Test results reveal the presence of asbestos in approximately half of the samples tested. Additionally, fibrous talc was found at varying levels in all samples.(79-83)

Finally, I have reviewed the report of Dr. Michael Crowley that discusses the different chemicals added to the fragrance constituents contained in Johnson's Baby Powder and Shower to Shower products (84)Based on his review, he has concluded that these chemicals may contribute to the potential carcinogenicity of talcum powder products.

Therefore, based on the scientific literature and testing results, it is my opinion that the presence of asbestos, heavy metals, fibrous talc, and fragrances are all biologically plausible explanations for talcum powder products causing ovarian cancer.

Biological Mechanisms

Evidence of Migration of Talcum Powder Products (Talc, Asbestos, Other Minerals) to the Ovary and Fallopian Tubes

Clinical and laboratory studies have shown that talcum powder products can migrate to the ovaries and fallopian tubes. An early surgical study in healthy premenopausal women found that inert particles placed in women's vaginas moved to their fallopian tubes within 30 minutes in two of the three patients studied.(85) Henderson et al. found talc particles in 10 of 13 (75%) of ovarian tumors studied using an extraction-replication technique.(86) The findings were replicated 8 years later, with all surgeons removing the ovaries wearing gloves with no talc, to ensure that surgical contamination was not the cause of the observed talc within ovaries.(87) This replication study found talc in all 9 samples studied—3 normal ovaries, 3 cystic ovaries, and 3 adenocarcinomas.

In another relevant clinical experiment regarding migration, the researchers placed 3 ml of ^{90m}Tc-labelled human albumin microspheres in women's vaginas one day before pelvic surgery.(88) Of the 21 women for whom the materials moved up from the cervical area, ovaries and fallopian tubes could be counted separate from the uterus in 14. Of these 14, 9 showed radioactivity in the fallopian tubes and ovaries, and 5 showed no radioactivity. In a pathological study as part of a case-control study of benign ovarian conditions, ovaries from 24 women were tested for presence of talc and asbestos by both electron microscopy and light microscopy.(64) All tested ovaries were found to have talc present. Only half of the 24 women reported a history of perineal talc exposure, which suggests additional routes of exposure to talc, such as inhaled powder. The presence of talc was not due to surgical gloves as all

surgeons wore talc-free gloves in this study. In another study employing microscopy (Raman), the study authors found talc particles in ovarian tissue samples from a woman with known perineal talc exposure that were not visible with other methods.(89)

Another study demonstrated migration of talc evaluated powder on medical gloves used to perform pelvic examinations (with gloved hand inserted into the vagina).(90) This study detected powder in the peritoneal fluid, fallopian tubes, and ovaries the following day after the pelvic examination in women exposed to powdered gloves but almost none in women exposed to unpowdered gloves. The differences between the two groups were statistically significant.

In 2007, Cramer described the presence of talc particles observed in a pelvic lymph node of a 68 year old woman with stage III serous ovarian carcinoma.(91) The authors used scanning electron microscopy to identify plate-like particulates in the 5-10 μm range within the lymph node, and energy dispersive X-ray spectroscopy revealed a magnesium and silicate signature compatible with talc. The authors also noted that talc could migrate through transport of the lymphatic system.

The results of these studies demonstrate talcum powder products can migrate from the perineal area to the ovaries and fallopian tube through both genital tract migration and inhalation. In my opinion it is biologically plausible that talcum powder products can reach the ovaries via migration from the perineum and via inhalation into the lungs, blood stream, and lymphatic system.

Inflammation in the Causal Pathway between Talcum Powder Product Use and Ovarian Cancer Development

The literature suggests that a likely pathway through which use of talcum powder products increases risk of ovarian cancer is through talc-induced inflammatory response.(92) As described above, it is well supported that talc can migrate through the female genital tract and settle in the area of the ovaries, fallopian tubes, and peritoneum (64, 86-88, 91, 93). Increased blood levels of biomarkers of inflammation have been linked to increased risk for ovarian cancer. A recent meta-analysis of 8 cohort studies found that women with high blood levels of c-reactive protein (a marker of increased systemic inflammation) had almost double the risk of developing ovarian cancer compared with women with low levels.(94)

Further evidence of the inflammation mechanism comes from studies which evaluate anti-inflammatories, like aspirin and NSAIDs, and reduction of risk of ovarian cancer. A pooled analysis of case-control studies published in 2014 showed that long-term daily use of aspirin (which blocks inflammation) decreased risk of ovarian cancer (odds ratio = 0.91; 95% CI = 0.84-0.99). Similar, but not statistically significant, results were shown for use of other nonsteroidal anti-inflammatory medications.⁽⁹⁵⁾ A 2018 meta-analysis found an 11% reduced risk of ovarian cancer with aspirin use (relative risk 0.89, 95% CI 0.83-0.95).⁽⁹⁶⁾ Aspirin and other nonsteroidal anti-inflammatory medications inhibit the inflammation-mediating enzyme, COX-1⁽⁹⁵⁾; COX-1 is frequently overexpressed in ovarian cancer tissue.^(97, 98)

Chronic inflammation may result in cell proliferation, inhibition of apoptosis, and secretion of mediators, that may promote tumorigenesis.⁽⁹²⁾ Factors related to the inflammation of the ovarian surface and tubal epithelium, such as incessant ovulation, endometriosis, and pelvic inflammatory disease, provide further evidence of inflammation and ovarian carcinogenicity. ⁽⁹⁹⁻¹⁰¹⁾

Talc exposure has also been linked to increased inflammation. It can induce granulomas and other inflammatory responses in vivo.^(102, 103) Injected into the pleural cavity to treat pneumothorax, talc stimulates an intra-pleural inflammatory reaction that causes pleural fibrosis and scarring, leading to obliteration of the pleural space and prevention of recurrent pneumothoraces.⁽¹⁰⁴⁾ In humans, elevated interleukin 8 (a chemotactic cytokine) occurs after pleural injection of talc.⁽¹⁰⁵⁾ In a study of over 227 patients treated with talc pleurodesis; about half received small particle talc, and half received large-particle talc. Patients who received small particle talc had significantly higher proinflammatory cytokines, particularly interleukin 8, in pleural fluid and serum after talc application.⁽¹⁰⁶⁾ In animal models, injection of talc into the pleura can cause local and systemic inflammatory responses⁽¹⁰⁷⁾ including elevated inflammation-related biomarkers c-reactive protein and interleukin 8⁽¹⁰⁸⁾ as well as VEGF, and TGF-beta.⁽¹⁰⁹⁾ This type of inflammation can induce neoplastic changes.⁽¹¹⁰⁾

Additional Evidence of Biological Mechanisms

Exposing human ovarian stromal and epithelial cells to talc resulted in increases reactive oxygen species (oxidative stress), cell proliferation and neoplastic transformation of cells.⁽¹¹⁰⁾ Similarly, in a recent *in*

vitro study by Fletcher et al., talc was applied in different concentrations, for varying numbers of hours, to epithelial ovarian cancer cell lines and normal ovarian epithelial cells.(111) As early as 24 hours post-treatment, they found increases in mRNA (gene expression) of pro-oxidant enzymes iNOS and MPO in talc-treated epithelial ovarian cancer cells and normal ovarian cells, compared with non-treated controls. Marked decreases in several antioxidant enzymes in talc-treated cells were also seen. This study supports the role of talc in inducing oxidative stress, providing a molecular basis for epidemiologic studies demonstrating an increased risk of ovarian cancer with perineal talcum powder product exposure.(111-113) Another *in vitro* study found that talc induced a biological effect by enhancing CA-125 in ovarian cancer cells and in normal cells.(114)

Talc application to human mesothelial cells in cell culture has also been shown to increase gene expression in 30 genes that are relevant to carcinogenesis, and asbestos application increased gene expression in over 200 genes.(115) In the same study, asbestos application to human ovarian epithelial cells increased gene expression in two genes at 8 hours and 16 genes at 24 hours. Many of the expressed genes are relevant to the carcinogenic process. Results from this experimental study show that talc causes a statistically significant increase in gene expression in mesothelial cells in several genes related to carcinogenesis, including activating transcription factor 3 (ATF3), which controls production of several markers of inflammation.(115)

Asbestos, which has been found in talcum powder products, has been classified by IARC as a known ovarian carcinogen after a systematic review of the epidemiological and biological science.(40) Two meta-analyses and one pooled analysis have addressed the association between asbestos exposure and risk of ovarian cancer.(71-73) The studies of asbestos and ovarian cancer were typically studies of cohorts with high levels of occupational or home asbestos exposure, and comparisons were made to the general population as controls. The most recent meta-analysis found that women exposed to asbestos had a relative risk dying of ovarian cancer of 1.77 (95% CI 1.37-2.28) compared with unexposed populations(71). The other meta-analysis found that women exposed to asbestos had a relative risk of developing or dying of ovarian cancer of 1.75 (95% CI 1.45-2.10) compared with unexposed women(72). An additional four cohort studies (73, 116-119), which were published after the date of the most recent meta-analysis(71),as well as the pooled analysis(73) found similar elevated risks of ovarian cancer in women with asbestos exposure.

IARC also lists mechanisms through which asbestos can cause cancer including: impaired fiber clearance leading to macrophage activation, inflammation, generation of reactive oxygen and nitrogen species, tissue injury, genotoxicity, aneuploidy and polyploidy, epigenetic alteration, activation of signaling pathways, and resistance to apoptosis.(41) Asbestos is another biologically plausible explanation for talcum powder products causing ovarian cancer.

It is my opinion, based on these studies, that talc and asbestos induce inflammation which results in cell proliferation, inhibition of apoptosis, and secretion of mediators, that may promote tumorigenesis. This adds to the weight of evidence and provides a plausible biological explanation for the association between genital talcum powder product use and ovarian cancer.

Another line of experiments in support of the biologically plausible mechanism for talcum powder products causing ovarian cancer were conducted in animals. A study with female rats showed that talc is absorbed through the pleural surface and rapidly disseminated throughout internal organs and lymph nodes.(120) Henderson et al found that talc placed in the uteruses or vaginas of female rats moved to the animals' ovaries by four days post-administration.(121)

In another study, exposure of rat ovaries to talc led to cyst formation and epithelial changes.(122) A methodology study discovered that talc caused superoxide anion generation and release from mouse macrophages.(123)

Animal experiments conducted by the National Toxicology Program (NTP) of the U.S. Department of Health and Human Services are highly relevant to the role of talc in carcinogenesis. An NTP rat study provided important "signal " information of talc toxicity relevant to talc and development of ovarian cancer.(124) In an inhalation study, male and female F344/N rats were exposed to daily talc aerosols of non-asbestiform talc, with appropriate controls. NTP concluded that there was clear evidence of carcinogenic activity of talc in female F344/N rats based on increased incidences of alveolar/bronchiolar adenomas and carcinomas of the lung, and benign and malignant pheochromocytoma of the adrenal gland. The NTP also concluded that there was some evidence of carcinogenic activity of talc in male F344 /N rats based on an increased incidence of benign and malignant pheochromocytoma of the adrenal gland.

In my opinion, these animal studies further demonstrate that talcum powder products and its attendant inflammation can induce carcinogenesis. This provides further evidence of a biologically plausible mechanism supporting causation of ovarian cancer from the use of talcum powder products.

Summary of Findings: Weight of the Evidence/Bradford Hill Analysis

The summary relative risk estimates from the most recent meta-analyses(34, 35) and the pooled analysis(39) indicate that women who have ever used talcum powder products in the perineal/genital areas (including use of sanitary napkins, diaphragms, underwear, and direct application) have approximately 22-31% increased risk of developing ovarian cancer compared with never-users.

This review of the association between talcum powder products in the perineal/genital area produced several clear findings. Below, they are outlined according to the aspects of causality as described by Bradford Hill.(43) The epidemiologic evidence in total, along with the biological and pathological evidence, fits virtually all of the Bradford Hill aspects for causation, namely: the strength of the association, consistency across populations, specificity, temporality, experiment, biologic gradient (dose-response), plausibility, coherence, and analogy.

Strength of the association and statistical significance: The meta-analyses and pooled analysis showed that risk of ovarian cancer among ever users of talcum powder products is 22-31% higher than in women who never used these products. A total of 28 case-control studies, 3 prospective cohort studies, 2 meta-analyses, and one pooled analysis were reviewed in depth. The meta-analyses found a statistically significant 24 – 25% increased risk of developing serous ovarian cancer—representing 52% of epithelial ovarian cancer cases(125) —in women who had ever used talcum powder products compared with never-users. The pooled analysis, which included data from 5 previously published and 3 unpublished case-control studies, found similar statistically significant increased risks for overall epithelial ovarian cancer and serous ovarian cancer (24% and 20%, respectively). Thus, when combining these studies through meta-analyses, the totality of the evidence shows a statistically significant increased risk of ovarian cancer with use of perineal talcum powder products. Viewed in the context of the high consistency of the study results across time, diverse study populations, and strong study

designs, bias and chance as explanation for the increased risk are unlikely. Further, my confidence in the reliability of the data on magnitude of the risk is enhanced. Therefore, my analysis of these studies strongly supports a causal association and, given the high prevalence of use of talcum powder products in this population, these levels of risk present a clinically significant public health concern. I placed high weight on this aspect of determination of causality.

Consistency of the association: Across the case-control and cohort studies, the association between use of talcum powder products and risk of ovarian cancer was highly consistent. As indicated above, the case-control studies included population-based and hospital-based studies from a diverse geographic area across the U.S., as well as Australia, Canada, the UK, Israel, Greece, and China. Of the 28 studies, 24 found odds ratio greater than 1.1 for ovarian cancer in women who had any perineal exposure to talcum powder products, compared with never users (1-6, 8-11, 13-23, 25-27). Of these 24 odds ratio estimates, 16 were statistically significant (95% confidence intervals excluded 1.0 or p value ≤ 0.05). Among the 8 studies which were not statistically significant, 7 had a sample size lower than that estimated to be needed to have power to detect a statistically significant result. Furthermore, the increased risk of ovarian cancer with use of talcum powder products has been seen in various race/ethnic groups as well as in diverse geographic areas around the world. While the cohort studies on average showed more attenuated relative risks of ovarian cancer in relation to use of talcum powder product use, these studies were not well designed to determine true risk for ovarian cancer and perineal talc use. Therefore, their results as a group do not negate the significant case-control study findings and the significant results of the meta-analyses and the pooled analysis.

The most recent and comprehensive meta-analysis by Penninkilampi *et al.*, assessed consistency across the studies included in their analysis by measuring heterogeneity with Cochran's Q statistic, with $P < 0.10$ indicating heterogeneity.(34) They then quantified the degree of heterogeneity using the I^2 statistic. The I^2 statistic represents the fraction of the total variability across studies that is due to heterogeneity. The authors categorized I^2 values of 25%, 50%, and 75% as corresponding to low, moderate, and high degrees of heterogeneity, respectively, which is typical for meta-analyses.(126) The authors found that there was no heterogeneity in the relative risk estimates for exposure to talcum powder products in the perineal area, or on diaphragms or sanitary napkins. Even though the 95% confidence intervals contained 1.0 in the cohort studies, given the clearly increased relative risk across the case-control

studies, the trend toward increased risk in two of the three cohort studies, and the results from the Penninkilampi et al. meta-analysis, it is my opinion that this did not occur by chance but is, in fact, a true causal relationship.

The consistency across studies, led by many investigators, using different study designs, and in diverse ethnic, racial, and geographic populations over a period of nearly 35 years weighs heavily as to the consistency and reliability of the data in favor of a causal risk. Accordingly, I placed significant weight on this factor in my causation analysis.

Specificity of the association: Use of talcum powder products is strongly associated with epithelial ovarian cancer. Analyses by histologic subtype of epithelial ovarian cancer found that serous ovarian cancer appeared to be most strongly and consistently related to talc exposure, although the pooled case-control project found associations some other subtypes of ovarian cancer. Mucinous cancers have been consistently found to be unrelated to use of these products. Therefore, the specificity aspect is present for epithelial ovarian cancer and certain subtypes. However, because many carcinogens have been shown to cause diverse and nonspecific morbidities, such as smoking, I weighed this aspect moderately in my causal analysis as compared to other Bradford Hill factors.

Temporality: The epidemiologic studies that looked at lifetime talcum powder product use supported that exposure to these products predated the diagnosis of ovarian cancer. I did not find any evidence of 'reverse causation', e.g., using talcum powder products to alleviate symptoms associated with ovarian cancer, nor do any investigators report finding reverse causation. Importantly, symptoms related to ovarian cancer (bloating, increased abdominal size, abdominal pain, pelvic pain, difficulty eating, feeling full quickly)(127) are not vaginal or perineal in origin, and would be unlikely to induce women to increase use of talcum powder products. The finding of temporality is an important component in the causal analysis and, as such, I place great weight in its applicability to the determination of causality.

Biologic gradient/ dose-response: The earlier studies were less likely to address dose-response associations. The larger, and more recent studies, however, collected important data that inform dose-response relationships. Many of the 28 case control studies found evidence of a dose-response effect. Most often, this took the form of lifetime numbers of applications of talcum powder products or years of use. Thus, while there were studies that did not look for or find a dose-response, the body of

literature when taken as a whole does indicate a dose-response effect. Some studies did not gather detailed dose data such as frequency of use or length of use. Others gathered either frequency of the use or duration of use, but not both. As with smoking, ascertainment of frequency x duration of exposure (cumulative exposure) is an optimal metric to determine true dose-response effects. The meta-analyses and the pooled analysis also found evidence of relationships between increasing amount of exposure to talcum powder products in the perineal/genital area (including frequency, years of use, and estimates of lifetime applications) and increased risk of developing epithelial ovarian cancer (i.e., dose-response relationships). Thus, the studies that accurately determined use of talcum powder products revealed evidence of dose-response effects. When present, the finding of a biologic gradient/dose-response is helpful in determining causation. The findings within the study data, particularly meta-analyses and the pooled analysis, thus, supports my causal analysis and I placed significant weight on this factor.

Plausibility: In my consideration of whether talcum powder products can cause cancer, I considered the data for biologically plausible mechanisms by which exposure to talc could result in ovarian cancer. In that regard, I assessed data and determined that talcum powder products can migrate from the perineum through the female genital tract to the ovaries; talcum powder products are found in ovarian and fallopian tube tissues; talcum powder products can induce an inflammatory response; and because of the inflammatory response, malignant transformation can occur. Support for these finding comes from reliable, peer-reviewed scientific literature which indicates that talcum powder products can migrate from the perineum up the genital tract to the fallopian tubes and ovaries and become imbedded in the ovarian tissue. Thus, it is biologically plausible that genital exposure to talcum powder products can result in exposure to the ovaries.

Data also plausibly indicates that inhalation of talcum powder products can result in exposure leading to cancer, including mesothelioma. Studies also show that talcum powder products can be absorbed and transported via the lymphatic system or blood stream. Therefore, inhalation of talcum powder products could result in similar ovarian exposure. Published scientific data shows that talc reaches the ovary and becomes imbedded in the ovarian tissue. There are reliable data to support that talc induces an inflammatory response which mediates oxidative stress, release of cytokines and resulting genotoxicity which can induce malignant transformation. Further, the presence of asbestos and other constituents in

the talcum powder products such as asbestos, heavy metals, and fragrance have been shown to induce cancer by similar mechanisms.

While I have considered the data that do not support the plausibility of talcum powder products' carcinogenicity, otherwise overwhelming and reliable evidence indicates that there are biologically plausible mechanisms by which talcum powder products can induce ovarian carcinogenicity. Talc and its constituents can reach the ovaries, induce an inflammatory response that leads to genotoxicity and to development of ovarian cancer. While this mechanism of carcinogenicity is not proven, it is highly biologically plausible based on the present scientific information and understanding. Therefore, I place significant weight on this aspect of determination of causality.

Coherence: The cause-and-effect interpretation of the data on talcum powder product use and risk of ovarian cancer clearly do not significantly conflict with the known facts about the natural history and biology of the disease. Increased inflammation has been linked to risk of ovarian cancer, and talc and other contents of talcum powder products elicit inflammatory responses within areas of the body in which they have been found (i.e. ovary, peritoneum, lymph nodes, etc.). By analogy, a similar mechanism has been reported by which asbestos causes ovarian cancer. These mechanisms are consistent with one another and the accepted understanding of the role of inflammation in carcinogenesis. While these factors support a causal association and my opinions in this regard, I do not weigh them quite as heavily as the strength and consistency of the association.

Experiment: As discussed above, the evidence from randomized controlled trials can provide strong support to observational evidence. However, here, randomized controlled trials are neither feasible nor ethical, similar to smoking and lung cancer. This is because ovarian cancer is a rare disease and typically takes decades to develop to be clinically diagnosable. In addition, because the effects of genital talcum powder product use could be harmful, it would be unethical to conduct a trial of this type. Furthermore, the studies involving migration of talc, the inflammatory process and its association with carcinogenesis all contribute in a compelling manner to the causal analysis. While there are experimental data supporting causation from cell studies and animal models, given the inability to conduct experimental studies in humans to test effects of talcum powder products on ovarian cancer development, there are no human experimental data. Despite this, data from reliable observational studies as described in this

report strongly support causation. Therefore, I placed slight weight to this aspect of determination of causality.

CONCLUSION

In conclusion, it is my professional opinion, stated to a medical and scientific degree of certainty, that based on the totality of the evidence, which includes epidemiological, biological, pathological and mechanistic data, perineal use of talcum powder products can cause ovarian cancer.

Tables: Epidemiological Studies of Talcum Powder Product Use and Risk of Ovarian Cancer

Table 1: Case-Control Studies

Study	Country	No. Cases	No. Non-cases	Source of participants	Odds Ratio All Ovarian Ca, Any Perineal Talc Use (95% CI)	Odds Ratio Serous Ovarian Ca, Any Perineal Talc Use (95% CI)	Dose-response?
/Schildkraut 2016 (1)	U.S.	584	745	Population	1.44 (1.11-1.86)	1.38 (1.03-1.85)	Yes, OR's: < 3600 apps 1.16 ≥ 3600 apps 1.67 p _{trend} < 0.01
Cramer 2016 (2)	U.S.	2041	2100	Population	1.33 (1.16-1.52)	1.42 (a) (1.19-1.69)	Yes > 24 talc-years: OR 1.49 p _{trend} = 0.02
Wu 2015 (3)	U.S.	1701	2391	Population	1.46 (1.27-1.69)	Not addressed	Yes, per 5-years talc: OR 1.14 (95% CI 1.09-1.20)
Kurta 2012 (4)	U.S.	902	1802	Population	1.4 (1.16-1.69)	Not addressed	Not addressed
Rosenblatt 2011 (5)	U.S.	812	1313	Population	1.27 (0.97-1.66)	1.47 (borderline) (0.84-2.56) 1.01 (invasive) (0.69-1.47)	No (lifetime number of apps, years of use)
Wu 2009 (6)	U.S.	609	688	Population	1.53 (1.13-2.09)	1.70 (1.27-2.28)	Yes, lifetime apps OR: ≤5200: 1.20 >5200 to ≤15600: 1.38 >15,600 to ≤52000: 1.34 >52000: 1.99

							$p_{trend} = 0.0004$
Moorman 2009 (7)	U.S.	1114	1086	Population	Whites: 1.04 (0.82- 1.33) Blacks: 1.19 (0.68- 2.09)	Not addressed	Not addressed
Merritt 2008 (8)	Australia	1576	1509	Population	1.17 (1.01- 1.36)	1.21 (1.03-1.44)	Yes, OR: None 1.0 > 0-10 yrs 1.13 > 10-25 yrs 1.08 > 25 yrs 1.29 $p_{trend} = 0.02$ (similar stat sign trend for serous)
Mills 2004 (9)	U.S.	256	1122	Population	1.37 (1.02- 1.85)	1.77 (1.12-2.8)	No (freq X dur), OR Never 1.0 Q1 1.03 Q2 1.81 Q3 1.74 Q4 1.06 $p_{trend} = 0.05$
Ness 2000 (10)	U.S.	767	1367	Population	1.5 (1.1-2.0)	Not addressed	No (duration only)
Cramer 1999 (11)	U.S.	563	523	Population	1.60 (1.18 - 2.15)	1.38 (borderline) (0.82, 2.31) 1.70 (invasive) (1.22, 2.39)	Yes, lifetime apps when fallopian tubes patent: OR < 3000: 1.54 3000- 10,000: 1.72 >10,000: 1.80
Wong 1999 (12)	U.S.	499	755 (non- GYN cancer patients)	Hospital	0.92 (.24-3.62)	1.2 (0.7-2.1)	No (duration only)

Godard 1998 (13)	Canada	170	170	Population	2.49 (0.94- 6.58)	Not addressed	Not addressed
Green 1997 (14)	Australia	824	855	Population	1.3 (1.1-1.6)	Not addressed	No (duration only, data not shown)
Cook 1997 (15)	U.S.	313	422	Population	1.5 (1.1-2.3)	1.70 (1.1-2.50)	No (cumulative lifetime days)
Chang 1997 (16)	Canada	450	564	Population	1.42 (1.08- 1.86)	1.34 (0.96-1.85)	No (frequency or duration)
Shushan 1996 (17)	Israel	200	408	Population	2.0 (p=0.04)	Not addressed	Not addressed
Cramer 1995 (18)	U.S.	450	454	Population	1.6 (1.2-2.1)	Not addressed	Not addressed
Purdie 1995 (19)	Australia	824	860	Population	1.27 (1.04- 1.54)	Not addressed	Not addressed
Tzonou 1993 (28)	Greece	189	200	Hospital	1.05 (0.28- 3.98)	Not addressed	Not addressed
Rosenblatt 1992 (20)	U.S.	77	46	Hospital	1.7 (0.7-3.9)	Not addressed	Yes: ≥ 37.4 years vs. < 37.4 years: OR 2.4
Chen 1992 (21)	China	112	224	Population	3.9 (0.9- 10.63)	Not addressed	Not addressed
Harlow 1992 (22)	U.S.	235	239	Population	1.5 (1.0-2.1)	1.4 (.9-2.2)	Yes, lifetime applications, OR: < 1000 : 1.3 1000- 10,000: 1.5 $> 10,000$: 1.8 $p_{trend} = 0.09$
Booth 1989 (23)	U.K.	235	451	Hospital	Daily 1.3 (0.8-1.0) Weekly 2.0 (1.3- 3.4)	Not addressed	Yes, RR: Never 1.0 Rarely 0.9 Monthly 0.7 Weekly 2.0 Daily 1.3 $p_{trend} = 0.05$

Harlow 1989 (24)	U.S.	116 border- line only	158	Population	1.1 (0.7-2.1)	Not addressed	Not addressed
Whittemore 1988 (25)	U.S.	188	539	Hospital + population	1.45 (p=0.06)	Not addressed	1-20 applications/ mo RR 1.27 (0.82-1.96) > 20 apps/mo RR 1.45 (0.94-2.22) No p _{trend} provided
Hartge 1983 (26)	U.S.	135	171	Hospital	2.5 (0.7-10.0)	Not addressed	Not addressed
Cramer 1982 (27)	U.S.	215	215	Population	1.92 (1.27- 2.89)	Not addressed	Not addressed

Table 2: Prospective Cohort Studies

Study Year Published	Country	No. Cases	No. Non-cases	Baseline Age	Years of Follow-up	RR All Ovarian Ca, Any Perineal Talc Use (95% CI)	RR Serous Invasive Ovarian Ca, Any Perineal Talc Use	Dose-response
Sister Study Gonzalez, 2016 (30)	U.S.	154	41,500	54.8	Median 6.6 years	0.73 (0.44-1.21)	Not addressed	Not addressed
Women's Health Initiative Houghton, 2014 (29)	U.S.	429	61,147	63.3	Mean 12.4 years	1.06 (0.87-1.28)	1.13 (0.84-1.51)	No (< 9 vs. 10+ years); no frequency data collected
Nurses Health Study Gertig, 2000 (31)	U.S.	307	78,323	36-61 years in 1982 (year of talcum powder product use data collected)	Not provided	1.09 (0.86-1.37) (ever use perineal talc vs. never use)	1.40 (1.02-1.91)	No (only frequency data collected, no duration data)
Nurses Health Study Gates, 2008 (32)	U.S.	210	600	36-61 years in 1982 (year of talcum powder product use data collected)	Not provided	1.24 (0.83-1.83) (≥ 1 /wk vs. < 1/wk)	1.48 (0.82-2.68) (≥ 1 /wk vs. < 1/wk)	Yes: RR's < 1/wk 0.98 1-6/wk 1.01 > 6/wk 1.44
Nurses Health Study Gates, 2010 (33)	U.S.	797	78,323??	6-61 years in 1982 (year of talcum powder product	Not provided	1.06 (0.89-1.28) (≥ 1 /wk vs. < 1/wk)	1.06 (0.84-1.35)	Not addressed

				use data collected)				

Table 3: Meta-analyses

Study	Number of Studies	Number of Cases	Relative Risk All Ovarian Ca, Any Perineal Talc Use (95% CI)	Relative Risk Serous Ovarian Ca, Any Perineal Talc Use (95% CI)	Dose-Response
Penninkilampi 2018 (34)	27	14,311	1.31 (1.24-1.39)	1.32 (1.22-1.43)	Yes: OR 1.32 for < 3600 applications; OR 1.42 for > 3600 applications
Berge 2017 (35)	27	Not provided, should be same as Penninkilampi above	1.22 (1.13–1.30)	1.24 (1.15–1.34)	Yes for duration and frequency: 1) RR per 10-year use 1.16 (95% CI 1.07-1.26); 2) RR per weekly use 1.05 (95% CI 1.04-1.07)
Langseth 2008 (36)	20	Not provided	1.35 (1.26-1.46)	Not addressed	Not addressed
Huncharek 2003 (37)	16	5260	1.33 (1.16-1.45)	Not addressed	No summary estimates calculated. Dose response addressed in 9/16 source studies: no dose-response apparent
Cramer 1999 (11)	14	3834	1.4 (1.2-1.5)	Not addressed	Not addressed
Gross 1995 (38)	10 (N=5 studies with adjusted data and limited to	1509	1.29 (1.02-1.63)	Not addressed	Not addressed

	epithelial ovarian cancers)				
Harlow 1992 (22)	6	1106	1.3 (1.1-1.6)	Not addressed	Not addressed

Table 4: Pooled Analysis

	Number of Studies	Number of Cases	Odds Ratio All Ovarian Ca, Any Perineal Talc Use (95% CI)	Odds Ratio Serous Ovarian Ca, Any Perineal Talc Use (95% CI)	Dose-Response All Ovarian Cancer
Terry 2013 (39)	8	8,525	1.24 (1.15– 1.33)	1.24 (invasive) (1.13–1.35)	Yes. OR (95% CI) by quartiles of lifetime applications vs. never use, non-mucinous cases only: Q1 1.18 (1.02-1.36) Q2 1.22 (1.06-1.41) Q3 1.22 (1.06-1.40) Q4 1.37 (1.19-1.58)

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Additional Materials and Data Considered

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2. American Cancer Society - Ovarian Cancer
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8. Cralley, Key et al. Fibrous and mineral content of cosmetic talcum products
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10. Deposition Transcript - Shripal Sharma (Berg v. J&J)
11. Deposition Transcript & Exhibits - John Hopkins (8/16/18, 8/17/18, 10/26/18, 11/5/18)
12. Deposition Transcript & Exhibits - Joshua Muscat (9/25/18)
13. Deposition Transcript & Exhibits - Julie Pier (9/12/18, 9/13/18)
14. Deposition Transcript & Exhibits - Linda Loretz (7/17/18, 10/1/18, 10/2/18)
15. Deposition Transcript of Alice Blount, April 2018
16. Deposition Transcript of Patricia Moorman (Ingham)
17. Expert Report of Jack Siemiatycki
18. Fair warning TalcDoc 15
19. Fair warning TalcDoc 5 - Exhibit 113 (JNJNL91_000022019)
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21. First Amended Master Long Form Complaint & Exhibits

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36. Hopkins Chart - Exhibit 24
37. Huncharek et al. Use of cosmetic talc on contraceptive diaphragms and risk of ovarian cancer: a meta-analysis of nine observational studies
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94. Park, Schildkraut, et al. Benign gynecologic conditions are associated with ovarian cancer risk in African-American women: a case-control study
95. Reference Manual on Scientific Evidence (rev 2011)
96. Reuters, Talck linked to OCVA risk in African American women
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100. Rothman, Greenland, Lash. Modern Epidemiology, 3rd Edition
101. Rothman, Pastides, Samet. Interpretation of epidemiologic studies of talc and ovarian cancer
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104. Trial Testimony of John Hopkins, Berg v. J&J (Oct. 2013)
105. US Dept. of Health & Human Service - Public Health Service, Agency for Toxic Substances and Disease Registry - "Toxicological profile for asbestos"
106. Van Gosen, Lowers et al. Using the geologic setting of talc deposits as an indicator of amphibole asbestos content
107. Virta. The phase relationship of talc and amphiboles in a fibrous talc sample
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109. Wehner, Hall et al. Do particles translocate from the vagina to the oviducts and beyond?
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113. Zuckerman D, D Shapiro. Talcum powder and ovarian cancer, National Center for Health Research, May 7, 2018. <http://www.center4research.org/talcum-powder-ovarian-cancer/>

EXHIBIT A

Curriculum Vitae

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EDUCATIONAL BACKGROUND

Residency, Primary Care Internal Medicine, 6/92, University of Washington School of Medicine, Seattle, WA
M.D., 6/89, New York Medical College, Valhalla, NY
Ph.D. in Epidemiology, 12/82, University of Washington, Seattle, WA
M.A. in Medical Sociology, 6/76, State University of New York at Buffalo,
B.A. in Sociology, 1/74, Boston University, Boston, MA

PROFESSIONAL POSITIONS

Division of Public Health Sciences, Fred Hutchinson Cancer Research Center, Seattle, WA
Director, FHCRC Prevention Center (2002 - 2012)
Full Member (2001 - present)
Associate Member (1997 – 2001)
Assistant Member (1996 - 1997)
Senior Staff Scientist, Associate in (1983 – 1985; 1992 - 1996)
Department of Epidemiology, University of Washington School of Public Health, Seattle, WA
Research Professor (2003 -)
Research Associate Professor (1999 – 2003)
Research Assistant Professor (1996 - 1999)
Clinical Instructor (1992 - 1996)
Department of Medicine, Division of Geriatrics
Adjunct Research Professor (2003 -)
Adjunct Research Associate Professor (1999 - 2003)
Department of Medicine, Division of General Internal Medicine
Clinical Instructor (1992 – 1996)
Clinical Nutrition Research Unit, University of Washington, Seattle WA
Affiliate Investigator (1996 – present)
Harborview Medical Center, Adult Medicine Clinic, Seattle, WA
Attending Physician (1992 - 1995)
University of Washington, Women's Primary Care Clinic, Seattle, WA
Attending Physician (1996)

HONORS and TRAINEESHIPS

- American College of Sports Medicine Citation Award, 2012
- McDougall Mentoring Award, Fred Hutchinson Cancer Research Center, 2011
- Komen for the Cure Scientific Advisory Council/Komen Scholars, 2010-2012
- University of Washington Roger E. Moe Award for Translational Research 2009
- The Joan P. Liman MD Award, Recipient, New York Medical College, 1989
- National Institute for Dental Research, Fellowship Award in Behavioral Dental Research, 1983
- National Cancer Institute Traineeship, 1980-1982

- University of Washington Public Health Traineeship, 1978-1979

PROFESSIONAL ACTIVITIES

Committee Memberships and Academic Consulting

- 2018 U.S. Dept. Health and Human Services Physical Activity Guidelines Advisory Committee, 2016-2018
- Member, External Advisory Board, Pennington Biomedical Research Center, Louisiana, 2018
- Reviewer, NIEHS Sisters Study, 2018
- Patient-Centered Outcomes Research Institute Advisory Panel on Clinical Trials, 2014-2016
- University of Alabama, Center for Exercise Medicine External Advisory Committee, 2016
- Program Committee Member, American Institute for Cancer Research 2016 Conference on Nutrition, Physical Activity, Obesity and Cancer
- Consortium Member: NCI Randomized Controlled Trials of Lifestyle Weight Loss Interventions for Genome-Wide Association Studies, 2016-
- AACR Cancer Prevention Committee, 2010-
- World Cancer Research Fund (WCRF) Continuous Update Project Panel, 2010-
- 2008 U.S. Dept. Health and Human Services Physical Activity Guidelines Advisory Committee, 2007- 2008 (Chair, Cancer Working Group)
- Cancer Prevention Research Institute of Texas, Prevention Review Committee, 2009-2015
- Chair, Transdisciplinary Research on Energetics and Cancer (TREC) Steering Committee 2006-7
- Chair, Cancer Interest group, the Obesity Society, 2006-7
- Steering Committee for International Position Paper and Consensus Conference on Women's Health and the Menopause, NHLBI-Lorenzi Foundation sponsors, 1998 – 2002
- International Advisory Board to the 4th International Symposium on Women's Health and Menopause, 2000 – 2001 and 2004
- Professional Advisory Committee, Breastcancer.org, 2003 –
- Women's Health Research Coalition, 2002
- Women's Health Initiative Committee Membership: Morbidity and Mortality (Co-Chair); Performance Monitoring Outcomes Committee (Chair); Coordinating Center Outcomes Scientific Committee (Chair); Coordinating Center Representative to WHI Program Advisory Committee, 1994-1995; Genetics Working Group; Cancer Biomarkers Working Group
- Consultant, *Moving Forward Study*, University of Illinois, Chicago (PI, Melinda Stolley), 2013-
- Consultant, *The Energy Balance and Breast Cancer Aspects studies: EBBA-I and EBBA-II*, Oslo University Hospital, Oslo, Norway (PI, Inger Thune), 2013-
- American Institute of Cancer Research Meeting Program Committee member, 2010, 2016
- Cancer Prevention Expert Panel, Pennington Biomedical Research Center (Baton Rouge, LA), 2010
- External Advisory Committee, Cooper Clinic, Dallas, Tx, April 2006
- Steering Committee, LISA Trial of Weight Loss for Breast Cancer Patients, Novartis Canada 2005 – 2007
- Chair, Breast Clinical Endpoints Committee, DANCE trial of testosterone patch safety, Proctor & Gamble, 2006-7
- External Reviewer for NCI Nutritional Epidemiology Program, 2005, 2013
- Data and Safety Monitoring Board, "Project Alive", Kaiser Oakland (B. Sternfeld, PI)
- Member, NCI Transdisciplinary Research Working Group, co-Chair section on Lifestyle, 2006
- Panels for American Cancer Society Guidelines on *Diet, Nutrition and Cancer Prevention* and Guidelines for Cancer Patients and Survivors (2001, 2003, 2005)
- Working Group for International Agency for Research on Cancer Handbook of Cancer Prevention: Volume 6 – Weight control and physical activity, 2000 – 2001
- Advisory Board for the Tomorrow Study (Alberta, Canada, Cancer Cohort Study), 1999 - 2001
- Advisor to The effects of weight loss and exercise on biomarkers of breast cancer risk- a randomized pilot trial (M. Harvie, A. Howell, Manchester, England)
- Participant, "Workshop on Physical Activity and Breast Cancer", National Action Plan on Breast Cancer, Nov. 1997

- Invitee, “Beyond Hunt Valley: Research on Women’s Health for the 21st Century”, Nov. 1997
- Participant, “Breast Cancer in Minorities”, National Action Plan on Breast Cancer, March 1999
- 2005 ASPO Annual Meeting Program Committee
- Member, Steering Committee for International Position Paper and Consensus Conference on Women’s Health and the Menopause, NHLBI-Lorenzi Foundation sponsors, 1998

Editorial Boards

- Cancer Prevention Research, 2008 - 2014
- Journal of Women’s Health, 1998 –
- Medscape Women's Health and Ob/Gyn & Women's Health, 2001 – 2002

Grant Reviewing

- Chair, Department of Defense (DOD) United States Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) Breast Cancer Research Program - Prevention, January 2017
- Member, Department of Defense (DOD) United States Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) Breast Cancer Research Program - Prevention, January 2018
- Florida Department of Health Research Program Peer Review, 2017
- Department of Defense (DOD) United States Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) Breast Cancer Research Program - Epidemiology, February, 2016
- NCI Omnibus: Biomarkers R03 & R21 SEP-12 Review Committee 2015
- NCI Omnibus: Cancer Management & Behavior 2014
- MD Anderson NCI CCSG Review 2013
- Department of Defense (DOD) United States Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) Breast Cancer Research Program Breakthrough Award, Epidemiology/Prevention 2013
- Department of Defense (DOD) United States Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) Breast Cancer Research Program Training-Epidemiology - Prevention (2 cycles) 2013
- NIH Special Emphasis Panel Member September 2012
- NIH PRDP Study Section Member 2008-2012 (ad hoc 2006-2008)
- Susan G. Komen for the Cure 2009 - 2013
- Cancer Prevention & Research Institute of Texas 2009 – 2015
- Qatar National Priorities Research Program 2010-2013
- Catalan TV3 Marató Call 2005, 2013
- San Diego State/UC San Diego Pilot Grant Reviewer 2012
- FHCRC and UW Pilot Grant Reviews yearly
- NCI Cancer Centers Review Group Ad Hoc Member May 2007
- Pennsylvania Interim Performance Review 2007, 2008, 2010, 2012
- Marsha Rivkin Center for Ovarian Cancer Research Grants 2012
- Memorial Sloan Kettering Cancer Center NCI CCSG Review 2007
- Department of Defense Breast Cancer Program Predoctoral Fellowship Grants, 2006
- Chair, NIH Special Study Section “Mechanisms of Physical Activity Behavior Change” 3/04
- NIH EDC-2 Special Study Section, Sept. 9-10, 1997
- Alberta Cancer Board Grants, 1998-2002 and other Canadian agencies, and for Spanish and Italian Foundations
- NCI Administrative Supplements for Disseminating Evidence-based Research Products 8/04
- Member, ACSM Research Review Committee 2004 – 2006

Journal Reviewing

- JAMA, Archives of Internal Medicine, American Journal of Epidemiology, Journal of the National Cancer Institute, Annals of Internal Medicine, European Journal of Cancer, British Journal of Cancer, Cancer Causes & Control, Cancer Epidemiology Biomarkers & Prevention, Annals of Epidemiology, Epidemiology, and Nutrition

College Fellowship and Membership

- The Obesity Society (Fellow 2003 -)
- American College of Sports Medicine (Fellow 2003 -)
- American College of Epidemiology (Fellow 1999 -)

Professional Licenses and Certification

- Board Certified, American Board of Internal Medicine, 1992
- Physician & Surgeon License, State of Washington, 7/21/91-2/18/18
- DEA License, Expires 2017, Schedules 2, 2N, 3, 3N, 4, 5

LEADERSHIP

- Director, FHCRC Prevention Center, 2002-2012
- Chair, TREC Steering Committee 2006-7
- Chair, Cancer Interest Group, Obesity Society 2007-8
- Chair, Cancer Subcommittee, DHHS Physical Activity Guidelines Advisory Committee 2016-18
- Member, Leadership Group, DHHS Physical Activity Guidelines Advisory Committee 2016-18
- Chair, Cancer Working Group, DHHS Physical Activity Guidelines Advisory Committee 2007-8
- Chair, Section on Mechanisms, IARC Handbook of Cancer Prevention 2002: Physical Activity and Weight Control, 2000-1
- Organized and Chaired Symposium on Physical Activity and Cancer, American College of Sports Medicine, St. Louis, June 2002

REFEREED PUBLICATIONS

(** refers to student papers under my supervision; ^ denotes papers from studies on which I was PI)

1983

1. Shy K, **McTiernan A**, Daling J, and Weiss N: Oral contraceptive use and the occurrence of pituitary prolactinoma. Journal of the American Medical Association 249:2204-2207, 1983.

1984

2. ^**McTiernan A**, Weiss N, and Daling J: Incidence of thyroid carcinoma in women in relation to reproductive and hormonal factors. American Journal of Epidemiology 120:423-435, 1984.
3. ^**McTiernan A**, Weiss N, and Daling J: Incidence of thyroid carcinoma in women in relation to radiation exposure and history of thyroid disease. Journal of the National Cancer Institute 73:575-581, 1984.

1985

4. **McTiernan A**, Chu J, and Thomas D: Cancer in whites in the Pacific Basin. In Fourth Symposium on Epidemiology and Cancer Registries in the Pacific Basin. National Cancer Institute Monograph 69:65-72, 1985.

1986

5. ^**McTiernan A**, Weiss N, and Daling J: Bias resulting from using the card-back system to contact patients in epidemiologic studies. American Journal of Public Health 76:71-73, 1986.
6. **McTiernan A**, Whitehead A, Thomas D, and Noonan E: Efficient selection of controls for multi-centered collaborative studies of rare diseases. American Journal of Epidemiology 123:901-904, 1986.
7. **McTiernan A**, Thomas D, Johnson L, and Roseman D: Risk factors for estrogen receptor-rich and estrogen receptor-poor breast cancers. Journal of the National Cancer Institute 77:849-854, 1986.
8. **McTiernan A** and Thomas D: Evidence for a protective effect of long-term lactation on risk of breast cancer: results from a case-control study. American Journal of Epidemiology 124:353-358, 1986.
9. ^Mueller B, **McTiernan A**, and Daling J: Level of response in epidemiologic studies using the card-back system to contact patients. American Journal of Public Health 76:1331-1332, 1986.

1987

10. [^]**McTiernan A**, Weiss N, and Daling J: Incidence of thyroid cancer in women in relation to known or suspected risk factors for breast cancer. Cancer Research 47:292-295, 1987.

1991

11. Rosenblatt KA, Thomas DB, **McTiernan A**, et al: Breast cancer in men: aspects of familial aggregation. Journal of the National Cancer Institute 83:849-54, 1991.
12. Demers PA, Thomas DB, Rosenblatt KA, **McTiernan A**, et al: Occupational exposure to electromagnetic fields and breast cancer in men. American Journal of Epidemiology 134:340-47, 1991.

1992

13. Thomas DB, Jiminez LM, **McTiernan A**, et al: Breast cancer in men: risk factors with hormonal implications. American Journal of Epidemiology 135:734-48, 1992.

1993

14. Stalsberg H, Thomas DB, Rosenblatt KA, Jiminez LM, **McTiernan A**, et al: Histologic types and hormone receptors in breast cancer in men--a population-based study in 282 North American men. Cancer Causes and Control 4:143-51, 1993.

1994

15. Thomas DB, Rosenblatt K, Jiminez LM, **McTiernan A**, et al: Ionizing radiation and breast cancer in men. Cancer Causes and Control 5:9-14, 1994.

1995

16. Bowen D, Green P, Kestin M, **McTiernan A**, Carroll D: Effects of decreasing dietary fat on psychological well-being. Cancer Epidemiology, Biomarkers, and Prevention 4:555-59, 1995.
17. **McTiernan A**, Rossouw J, Manson J, et al: Informed consent in the Women's Health Initiative. Journal of Women's Health 5:519-529, 1995.

1996

18. Prentice R, Rossouw JR, Johnson, SR, Freedman LS, **McTiernan A**. The role of randomized controlled trial in assessing the benefits and risks of long-term hormone replacement therapy: example of the Women's Health Initiative. Menopause, 1996;3:71-76.
19. **McTiernan A**, Stanford JL, Weiss NS, Daling JR, Voigt LF: Occurrence of breast cancer in relation to recreational exercise in women age 50-64 years. Epidemiology 1996;7:598-604.

1997

20. Burke W, Peterson G, Lynch P, Botkin J, Daly M, Garber J, Kahn MJE, **McTiernan A**, Offitt K, Thomson E, Varricchio C, for the Cancer Genetics Studies Consortium. Recommendations for follow-up care of individuals with an inherited predisposition to cancer. 1. Hereditary nonpolyposis colon cancer. JAMA 1997;277:915-919.
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1998

23. Women's Health Initiative Study Group. Design of the Women's Health Initiative Clinical Trial and Observational Study. Controlled Clinical Trials 1998;19:61-109.
24. **McTiernan A**, Stanford J, Daling J, Voigt L: Prevalence and correlates of physical activity in women aged 50-64 years. Menopause 1998;5:95-101.
25. [^]**McTiernan A**, Kumai C, Bean D, Hastings R, Schwartz R, Ulrich N, Gralow J, Potter J. Anthropometric and hormone effects of an 8-week exercise-diet intervention in breast cancer patients: results of a feasibility pilot study. Cancer Epidemiology Biomarkers Prevention 1998;7:477-81.
26. Hoffman-Goetz L, Apter D, Demark-Wahnefried W, Goran M, **McTiernan A**, Reichman M. Mechanisms for an association between physical activity and breast cancer. Cancer (supplement) 1998;83:621-628.
27. **McTiernan A**, Ulrich N, Slate S, Potter J. Physical activity and cancer etiology: associations and mechanisms. Cancer Causes and Control 1998;9(5)487-509.

1999

28. Cheblowski RT, **McTiernan A**. Elements of informed consent for Hormone Replacement Therapy in patients with diagnosed breast cancer. Journal of Clinical Oncology 1999;17(1):130-42.
29. ^Negri E, Ron E, Franceschi S, DalMaso L, Mark SD, Preston-Martin S, **McTiernan A**, et al. A pooled analysis of thyroid cancer case-control studies: Methods. Cancer Causes and Controls 1999;10:131-142.
30. ^Negri E, DalMaso L, Ron E, LaVecchia C, Mark SD, Preston-Martin S, **McTiernan A**, et al. Menstrual and reproductive factors and thyroid cancer. Cancer Causes and Controls 1999;10:143-155.
31. ^LaVecchia C, Ron E, Franceschi S, DalMaso L, Mark SD, Chatenoud L, Braga C, Preston-Martin S, **McTiernan A**. Oral contraceptives, menopausal replacement treatment and other female hormones and thyroid cancer. Cancer Causes and Controls 1999;10:157-166.
32. Durfy S, Bowen D, Burke W, **McTiernan A**, et al. Attitudes and interest in genetic testing for breast and ovarian cancer susceptibility in diverse groups of women in Western Washington. Cancer Epidemiology Biomarkers and Prevention 1999;8:369-376.
33. ^**McTiernan A**, Ulrich CM, Yancey D, Slate S, Nakamura H, Oestreicher N, Bowen D, Yasui Y, Potter J, and Schwartz R. The Physical Activity for Total Health (PATH) Study: rationale and design. Medicine and Science in Sports and Exercise 1999;31:1307-1312.
34. **McTiernan A**, Potter J, Bowen D, Schwartz R. Exercise clinical trials in cancer prevention research: a call to action. Cancer Epidemiology Biomarkers and Prevention 1999; 8:201-207.
35. Bowen D, **McTiernan A**, Burke W, Powers D, Pruski J, Durfy S, Gralow J, Malone K. Participation in breast cancer risk counseling among women with a family history. Cancer Epidemiology Biomarkers and Prevention 1999; 8:581-586.
36. Rosenblatt KA, Thomas DB, Jimenez LM, Fish B, **McTiernan A**, et al. Diet and breast cancer in men. Cancer Causes and Control 1999;10:107-113.
37. ^Franceschi S, Preston-Martin S, DalMaso L, Negri E, LaVecchia C, **McTiernan A**, et al. A pooled analysis of thyroid cancer case-control studies. IV. Benign thyroid diseases. Cancer Causes and Control 1999;10:583-595.
38. ^LaVecchia C, Ron E, Franceschi S, DalMaso L, Mark SD, Chatenoud L, Braga C, Preston-Martin S, **McTiernan A**. A pooled analysis of thyroid cancer studies. Anthropometric factors. Cancer Causes and Control 1999;10:583-595.

2000

39. Burke W, Culver JB, Bowen D, Lowry D, Durfy S, **McTiernan A**, Anderson, MR. Genetic counseling for women with an intermediate family history of breast cancer. American Journal of Medical Genetics 2000;90(5):361-8.
40. **McTiernan A**. The associations of energy balance and body mass index with breast cancer risk in United States women from diverse racial and ethnic backgrounds. Cancer 2000;88:1248-1255.
41. Bowen DJ, **McTiernan A**, , Rosenberg E, Powers P, Feng Z: Recruiting women into a smoking cessation program to control weight: who might quit? Women and Health 2000;31(4):41-58.
42. Wingo PA, Calle EE, **McTiernan A**. How does breast cancer mortality compare with other cancers and cardiovascular disease at different ages in U.S. women? Journal of Women's Health 2000;9:999-1006.
43. **McTiernan A**. Physical Activity and the Prevention of Breast Cancer. Medscape. Invited as Expert Opinion. October 2000; 5(5). Available at <http://www.medscape.com/Medscape/WomensHealth/journal/2000/v05.n05/wh7419.mcti/wh7419.mcti-01.html>

2001

44. **Young SYN, Gunzenhauser JD, Malone KE, **McTiernan A**. The relationship between body mass index and asthma in the military population of the northwestern United States. Archives Internal Medicine 2001;161:1605-1611.
45. Davidoff R, **McTiernan A**, Constantine G, Davis KD, Balady GJ, Mendes LA, Rudolph RE, Bowen, DJ. Echocardiographic evaluation of women previously treated with fenfluramine: Long-term follow-up of a randomized, double-blind, placebo-controlled trial. Archives of Internal Medicine. 2001;161:1429-1436.
46. Marrett L, Theis B, Ashbury FD, and an Expert Panel. Workshop report: physical activity and cancer prevention. (member of the expert panel). Chronic Diseases in Canada 2001;21:143-149.
47. La Vecchia C, Brinton L, **McTiernan A**. Menopause, hormone replacement therapy and cancer. Maturitas 2001; 39: 97-115.
48. **McTiernan A**, Burke W, Bars J, et al. Comparison of two breast cancer risk estimates in women with a family history of breast cancer. Cancer Epidemiology Biomarkers and Prevention 2001;10: 333-338.

49. ^Bosetti C, Kolonel L, Negri E, Ron E, Franceschi S, Dal Maso L, Galanti MR, Mark SD, Preston-Martin S, **McTiernan A**, Land C, Mabuchi K, Jin F, Wingren G, Hallquist H, Glatte E, Lund E, Levi F, Linos D, La Vecchia C. A pooled analysis of case-control studies of thyroid cancer: fish and shellfish consumption. Cancer Causes and Control 2001;12:375-382.
 50. Shors AR, Solomon C, **McTiernan A**, White E. Melanoma risk in relation to height, weight, and exercise (United States) Cancer Causes and Control 2001; 12(7):599-606. Cancer Causes Control. 2001 Sep;12(7):599-606.
 51. Tavani A, La Vecchia C, Brinton LA, **McTiernan A**. Hormone replacement therapy and risk of endometrial cancer. Tumori. 2001 Sep-Oct;87(5):S20-1.
 52. LaVecchia C, Brinton LA, **McTiernan A**. Hormone replacement therapy and breast cancer risk: epidemiology. Journal fur Menopause 2001;8:5-7.
 53. Friedenreich C, Marrett LD, Members of the Canadian Breast Cancer Initiative Working Group on Primary Prevention of Breast Cancer and an Expert Panel. Workshop report: identification of research needs in breast cancer etiology. Chronic Diseases in Canada 2001;22:41-49 (member of the Expert Panel).
- 2002**
54. ^**Irwin ML, **McTiernan A**. Exercise effect on body weight in postmenopausal women: the Physical Activity for Total Health Study. In RA Lobo, PG Crosignani, R Paoletti, F Bruschi (eds). Women's Health and Menopause: New Strategies – Improved Quality of Life. Dordrecht, Kluwer Academic Pub. 2002, pp. 345-352.
 55. Chlebowski RT, Aiello E, **McTiernan A**. Weight loss in breast cancer patient management. J. Clinical Oncology 2002;20(4):1128-1143.
 56. ^**Slate S, Yasui Y, Ulrich C, **McTiernan A**. Mailing strategies and recruitment into an intervention trial of the exercise effect on breast cancer biomarkers. Cancer Epidemiology Biomarkers and Prevention 2002; 11: 73-77.
 57. Hendrix S, Clark A, Nygaard I, Aragaki A, Barnabei V, **McTiernan A**. Pelvic organ prolapse in the Women's Health Initiative: gravity and gravidity. Am J. Obstet Gynecol 2002 Jun;186(6):1160-6.
 58. Wenger NK, Paoletti R, Lenfant CJM, Pinn VW, Barrett-Connor E, Birkhauser MH, Brinton LA, Collins A, Collins P, Crosignani PG, Dennerstein L, Ettinger B, Gustafson JA, Guthrie J, Henderson VW, Hendrix S, Klein BEK, LaVecchia C, Lindsay R, Maggi A, McGowan JA, **McTiernan A**, Nilsson S, Redford M, Resnick SM, Rossouw JE, Santoro N, Sherman SS. Executive summary. In International Position Paper on Women's Health and Menopause: a Comprehensive Approach. Wenger NK, Paoletti R, Lenfant CJM, Pinn VW (eds). NIH Publication No. 02-3284. 2002, pp. 1-22.
 59. LaVecchia C, Brinton L, **McTiernan, A** Hormone replacement therapy, related therapies, and cancer. In International Position Paper on Women's Health and Menopause: a Comprehensive Approach. Wenger NK, Paoletti R, Lenfant CJM, Pinn VW (eds). NIH Publication No. 02-3284. 2002, pp.223-250.
 60. Barrett-Connor E, Hendrix S, Ettinger B, Wenger NK, Paoletti R, Lenfant CJM, Pinn VW, Birkhauser MH, Brinton LA, Collins A, Collins P, Crosignani PG, Dennerstein L, Gustafson JA, Guthrie J, Henderson VW, Klein BEK, LaVecchia C, Lindsay R, Maggi A, McGowan JA, **McTiernan A**, Nilsson S, Redford M, Resnick SM, Rossouw JE, Santoro N, Sherman SS. Best clinical practices: a comprehensive approach. In International Position Paper on Women's Health and Menopause: a Comprehensive Approach. Wenger NK, Paoletti R, Lenfant CJM, Pinn VW (eds). NIH Publication No. 02-3284. 2002, pp. 271-288.
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MANUSCRIPTS SUBMITTED FOR PUBLICATION

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2. Lofterød T, Frydenberg H, Eggen AE, **McTiernan A**, Mortensen ES, Wist EA, Akslen LA, Reitan JB, Wilsgaard T, Thune I. Triglycerides and weight change throughout life influence breast cancer development. The EBBA Life study. Submitted to Cancer Causes & Control 2016.
3. Mason C, deDieu Tapsoba J, Duggan C, Wang CY, Alfano CM, **McTiernan A**. Disordered eating behaviors and weight loss outcomes in a 12-month randomized trial of diet and/or exercise intervention in postmenopausal women. Submitted to American Journal of Clinical Nutrition 2018.
4. Chan DS, Abar L, Cariolou M, Nanu N, Greenwood DC, Bandura EV, **McTiernan A**, Norat T. World Cancer Research Fund International – Continuous Update Project: systematic literature review and meta-analysis of cohort studies on physical activity, adiposity, and weight change and breast cancer risk. Submitted to British Medical Journal. 2018

INVITED SCIENTIFIC PRESENTATIONS (does not include conference abstracts)

1. "Women's Health and the Women's Health Initiative." Fred Hutchinson Cancer Research Center, WHI Clinical Center Staff Trainings, 1993-1997.
2. "The Women's Health Initiative: An Overview." University of Washington, Department of Epidemiology Seminars, February 8, 1994.
3. "Risk Assessment for Breast Cancer." University of Washington, Department of Surgery Breast Cancer Conference, April 26, 1994.
4. "Risk Assessment for Breast Cancer." Breast Cancer in Young Women, University of Washington Continuing Education Conference, August 6, 1994.
5. "Assessing Individual Risk for Breast Cancer." Cancer in Lesbians Symposium, Fred Hutchinson Cancer Research Center, December 2, 1994.
6. "Breast Cancer in High Risk Populations: Women's Health Initiative." Fred Hutchinson Cancer Research Center Scientific Retreat, December 7, 1994.
7. "The Women's Health Initiative." Invited presentation at American Society for Preventive Oncology, Women's Cancers Study Group Meeting, March 11, 1995.
8. "Prevention in Practice and Trials." Current Concepts in the Early Detection of Breast Cancer, Multicare, Madigan Army Medical Center, and American Cancer Society 3rd Annual Oncology Conference, April 11, 1995.
9. "Exercise and Breast Cancer." Beating Breast Cancer in the '90's: What Everyone Needs to Know about Breast Cancer, University of Washington/Fred Hutchinson Cancer Research Center, April 23, 1996.
10. "Women's Health Initiative." Women's Health Grand Rounds, University of Washington Medical Center-Roosevelt, January 6, 1996.
11. "Exercise and Cancer." Interdisciplinary Cancer Course, Fred Hutchinson Cancer Research Center, March 26, 1997.
12. "Exercise and Breast Cancer." Nutrition Seminar, Department of Nutrition, University of Washington School of Public Health, April 10, 1997.
13. Panel Discussant, "Epidemiologic Issues", NAPBC Workshop on Physical Activity and Breast Cancer, Nov 13-14, 1997.
14. "Diet and Exercise" Breast Cancer Forum: Clinical Implications of Current Research, FHCRC, October 7, 1998.
15. "Exercise and Breast Cancer" American College of Sports Medicine, Seattle, WA, June 2, 1999.
16. "Physical Activity and Reproductive Hormones" Cooper Institute Conference on Physical Activity and Cancer, Dallas, Texas, November 5-7, 2000
17. "Weight Matters in Breast Cancer Prevention and Rehabilitation" Oncology Grand Rounds. Southwest Cancer Center at University Medical Center, Lubbock, Texas, March 2001
18. "Body mass, physical activity, and sex hormones in postmenopausal breast cancer patients". American Cancer Society Science Writers Conference, April 2001

19. "Obesity and Women's Cancer" Keynote Lecture, North American Association for the Study of Obesity, October 2001.
20. "Physical Activity and Breast Cancer", Women's Sports International, St. Louis, June 2002.
21. "Exercise and Breast Cancer", FHCRC Oncology Grand Rounds, October 2002.
22. "Physical Activity after Cancer: Physiologic Outcomes" in Exercise and the Cancer Survivor: What Should we Recommend?, American Dietetic Association Food and Nutrition Conference and Exhibition, Philadelphia, October 2002.
23. ** "Exercise and the Prevention of Colorectal Cancer" European School of Oncology Second Colorectal Cancer Conference, Rome, Italy, October 2002.
24. "Energy Balance – an Etiologic Factor in Human Cancer: Randomized Trial of Exercise Effect on Breast Cancer Biomarkers." Oslo Norway, July 2002.
25. "Exercise and Breast Cancer: Impact on Prevention and Recurrence" The Gibson Lecture in Cancer Prevention Endowed Lectureship, University of Virginia School of Medicine, February 26, 2003
26. "Exercise, Body Fat, and Breast Cancer" Florence Ettelson Memorial Lectureship Medicine Grand Rounds, Providence St. Vincent Medical Center, Portland, OR October 2003
27. "Exercise and Breast Cancer" U. Washington Geriatrics Grand Rounds October 2003
28. "Body Mass Index & Breast Cancer Risk" Challenges & Controversies in Breast Cancer, U Washington School of Medicine CME, October 2003
29. "Diet and Physical Activity" 2nd Emerging Trends in Adjuvant Therapy of Breast Cancer Conference, New York City, October 2003.
30. "Exercise in the Prevention of Breast and Colon Cancer" New England American College of Sports Medicine, November, 2003.
31. "Managing Toxicities of Therapy: Weight Loss and Exercise" School of Breast Oncology, November 2003
32. "Exercise and Breast Cancer Prevention" U. Hawaii, January 2004
33. ** "Obesity and Cancer" 2nd International Conference on the Future of Supportive Therapy in Oncology, St. Kitts, Carribean, February 2004
34. "Exercise and Breast Cancer" University of Alabama at Birmingham, CNRC/Nutrition Sciences Seminar Series, March 2004
35. "WHI Estrogen plus Progestin and Breast Cancer Results" FHCRC Gynecologic Cancer Research Program, March 2004
36. ** "Exercise Effects on Total Body Fat, Intra-Abdominal Fat, Insulin, Leptin, and the Metabolic Syndrome in Menopause" Plenary Session, 5th International Symposium on Women's Health and Menopause, Florence, Italy, April 2005
37. "Exercise and Women's Health" University of Virginia, May 2004
38. "Colon ca, biomarkers, and exercise" American College of Sports Medicine, 2004
39. "Obesity Management in Cancer Patients" ASCO, June 2004
40. ** "Effect of Physical Activity on Breast and Colon Cancer Biomarkers" Ireland/Northern Ireland/NCI Cancer Consortium Seminar on Obesity and Cancer, Dublin, Ireland, September 2004
41. "Exercise Trials in Cancer Prevention" AACR Frontiers in Cancer Prevention, Seattle, WA October 2004
42. "Physical Activity, Endogenous Hormones, and Cancer Etiology" Plenary Session AACR Frontiers in Cancer Prevention, Seattle, WA October 2004
43. "Obesity in Breast Cancer Patients" School of Breast Oncology, Atlanta, Georgia, November 2004
44. "Nutrition, Physical Fitness, and Cancer" Aultman Cancer Center, Canton, Ohio, November 2004
45. "Effects of Menopausal Hormone Therapy and Tamoxifen on Mammographic Density" University of Virginia, Department of Radiology, February 2005.
46. "Optimizing Health Outcomes" in Oncology Care in the 21st Century: Integrating Care along the Health Care Continuum, Arthur G. James Cancer Hospital Ohio State University, February 2005
47. "Obesity, Exercise, and Breast Cancer", Tyler, Texas Breast Cancer Conference (talks to oncologists and lay audiences) March 2005
48. "Breast Fitness" talk to women's health providers, Anchorage, Alaska, May 2005
49. "Low Carb Diets: Will They Be Effective in Reducing Breast Cancer Risk?" ASCO, Orlando 2005.
50. ** "Biologic mechanisms involved in the association between physical activity and cancer: results from recent

- randomized controlled intervention trials” Eurocancer, Paris, June 2005.
51. ** “Exploring Mechanisms Relating Energy Balance and Cancer” IARC, Lyon, France, June 2005.
 52. “Prevention of New and Recurrent Cancers: Lifestyle and Chemoprevention” and “Cancer Screening and Management: The PCP's Role” Issues in Aging Conference, New Orleans, July 2005
 53. "Exercise and Cancer Prevention" Rockefeller, NYC, September 2005
 54. ** “Open Forum of Breast Health”, Mexico City, Mexico, October 2005
 55. “Breast Fitness: Exercise for Breast Cancer Patients and Survivors”, Cancer Wellness Center Northbrook, IL, November 2005
 56. “Obesity in Breast Cancer Patients”, School of Breast Oncology, Atlanta GA, November 2005
 57. "Insulin Resistance Syndrome and Cancer Risk", International Conference on Metabolic Syndrome, San Francisco, November 2005
 58. “Selected Major Findings from the OS Results: Breast Cancer”, WHI Conference, Bethesda, February 2006.
 59. “Intermediate Endpoints in Energy Balance and Physical Activity Trials” NCI Workshop on State of the Evidence for a Weight Control Trial to Prevent Breast Cancer, Bethesda, March 2006.
 60. “Physical Activity and Cancer Recurrence and Survival”, Symposium: "Physical Activity across the Cancer Continuum" for the CDC International Congress on Physical Activity and Public Health, Atlanta, April 2006
 61. “Exercise, Estrogens, and Breast Cancer: Physical Activity Trials” American College of Sports Medicine, May 2006.
 62. “Exercise and Nutrition in Chemoprevention” WCRF/AICR International Research Conference, Washington DC, July 2006.
 63. ** “Exercise and Cancer Prevention”. National University of Singapore, Singapore, July 2006.
 64. ** “Breast Cancer Prevention”, “Lifestyle, Diet, and Breast Cancer”, “Lifestyle changes may reduce the risk of recurrence” Mexican Association of Breast Diseases 5th Annual Meeting, Leon, Mexico, August 2006.
 65. “WHI and Breast Cancer” Seattle Gynecological Society, Seattle, September, 2006
 66. "Physical Activity, Weight Control, and Cancer Prevention” Dana Farber Cancer Center Channing Laboratory and Harvard School of Public Health Seminar Series Speaker, October 2006.
 67. “Obesity in Breast Cancer Patients”, School of Breast Oncology, Atlanta GA, November 2006
 68. “Energy Balance and Cancer: Human Intervention Studies” NCI Energy Balance Working Group, Bethesda, MD, January 2007
 69. “Overweight, Obesity, and Sedentary Lifestyle in Breast Cancer Prognosis”. Interdisciplinary Science, Health Promotion, and Disease Prevention. Pasadena, CA. May 2, 2007.
 70. “Transdisciplinary Research to Elucidate the Pathways Linking Components of Energy Balance to the Cancer Process” Transatlantic Research and Innovation Symposium. Research Triangle Park, North Carolina, May 3, 2007.
 71. “Obesity, Physical Activity, & Breast Cancer” University of Washington CNRU May 11, 2007
 72. “Women’s Health Initiative Clinical Trials” Northwestern University Clinical Research Educational Conference, Chicago, May 18, 2007.
 73. “Exercise and Weight Loss in Women and Men” Northwestern University Dept of Preventive Medicine, May 18, 2007.
 74. FASEB Energy Balance, Body Fat & Disease, “Exercise and Cancer Prevention”, and chair of session “Exercise and Cancer Prevention & Prognosis” Indian Wells, CA, August 2007
 75. MD Anderson Cancer Prevention Grand Rounds, “Overweight, Obesity, Physical Activity, and Breast Cancer Prevention” Houston, Sept 2007
 76. MD Anderson Integrative Medicine Program Lecture Series talk “Obesity, Weight Loss, and Physical Activity for Cancer Patients and Survivors” Houston, Sept 2007
 77. **Breast Health Global Initiative “Primary prevention of breast cancer: lifestyle changes, diet, western lifestyle”, Budapest, Hungary, October 2007
 78. “Obesity in Breast Cancer Patients”, School of Breast Oncology, Atlanta GA, November 2007
 79. “Breast Cancer: Women at Risk and New Strategies for Prevention”, Practicing Clinicians Exchange, San Francisco, CA November 2007
 80. “Exercise Effect on Inflammation and Other Cancer Biomarkers”, Southeast ACSM, Birmingham, AL, February 2008
 81. “Professional Development for Women”, Southeast ACSM, Birmingham, AL, February 2008
 82. “Exercise and Body Composition Change Effects on Sex Hormones in Postmenopausal Women”, AACR – TREC

Markers & Mediators, Virginia, February 2008

83. "Obesity in Breast Cancer Risk and Prognosis", Case Western University, Cleveland, OH, March 2008
84. "Exercise Interventions in Breast Cancer Prevention and Outcomes", Cleveland, OH, March 2008
85. "TREC Talk", Cancer Prevention and Research Center Retreat, Coeur d' Alene, ID, March 2008
86. ** "Fitness vs. Fatness: Evidence from Epidemiologic and Intervention Studies on the Separate and Combined Effects of Physical Activity and Obesity on Cancer Risk", International Physical Activity Meeting, Amsterdam, April 2008
87. "Influence of Exercise on Immune Function: Possible Link to Breast Cancer", ACSM, Indianapolis, May 2008
88. "Breast Cancer Prevention and Survivorship through Lifestyle and Chemoprevention", Memorial Sloan Kettering Cancer Center, New York City, NY, September 2008
89. ** "Early Detection, Diet, Physical Activity, and Cancer", Women in High Places meeting, Riyadh, Saudia Arabia, October 2008
90. ***"Diet and Breast Cancer", Saudi Arabian Cancer Conference, Riyadh, Saudia Arabia, October 2008
91. "Physical Activity & Weight Control in Breast Cancer Prevention & Prognosis", Alaska Conference: "Reducing the Risk, Advancing the Cure: New Recommendations, New Options for Primary Care Providers and Survivors." Televised from Seattle, October 2008
92. "Lessons Learned from Real-Life Lifestyle Interventions", The Obesity Society, Phoenix, AZ, October 2008
93. "Breast Cancer: Weight Loss and Exercise", School of Breast Oncology, Atlanta, GA, November 2008
94. "Fitness vs. Fatness in Breast Cancer Risk and Prognosis", Frontiers of Cancer Prevention, Washington, DC, November 2008
95. "Effects of Exercise and Obesity on Inflammation and Cancer Risk", University of Washington, DERC Seminar Series, February 2009
96. "Does Weight Loss Reduce Cancer Risk?" The Obesity Society, October 2009.
97. Roger E. Moe Award for Translational Research Lecture "Effects of Weight and Physical Activity on Breast Cancer Prognosis" University of Washington *Current Concepts and Challenges in Breast Cancer* October 2009
98. "Lessons learned from physical activity (exercise) interventions" AICR Annual Research Conference on Food, Nutrition, Physical Activity and Cancer, Washington, DC, November 2010
99. "Weight Loss and Exercise" School of Breast Oncology, Atlanta GA, November 2010
100. "Transdisciplinary studies of weight loss and exercise interventions in women at increased risk for breast cancer", AACR, Washington, DC, April 2010
101. "Exercise Effects on Breast Cancer Biomarkers", International Society for Behavioral Nutrition & Physical Activity, Minneapolis, MN, June 2010
102. ***"Physical Activity & Cancer" Lecture, Helsedirektoratet (Directory of Health), Oslo, Norway, December 2010
103. "Physical Activity, Weight Control and Cancer Prevention" Physical Activity and Nutrition seminar series University of Michigan. The School of Kinesiology, February 2011.
104. "Physical Activity in Cancer Prevention" American College of Sports Medicine President's Talk, Denver, CO, June 2011
105. "Breast Cancer Prevention" Foundation for Care Management, Lakewood, WA, January 2011
106. "Breast Cancer Prevention" Foundation for Care Management, Coupeville, WA, February 2011
107. "Inflammation, Insulin, & Obesity in Breast Cancer Survival", University of Texas Southwestern Medical Center, Dallas, Texas, September 2011
108. "Interventions in cancer survivors; issues and challenges in this population", Institute of Medicine Workshop "The Role of Obesity in Cancer Survival and Recurrence", Washington, DC, October 31-November 1, 2011
109. "Weight Loss and Exercise" School of Breast Oncology, Atlanta GA, November 2011
110. ***"Obesity, Physical Activity, & Related Mechanisms in Breast Cancer Survival", Norwegian Congress in Oncology, Oslo, Norway, November 2011
111. "Impact of Obesity on Cancer " Swedish Hospital Medical Center CME, Seattle, WA May 2012
112. "Effects of Weight Loss and Physical Activity on Cancer Risk Factors: Evidence from Randomized Trials", University of Hawaii, July 2012
113. "The Impact of Intentional Weight Loss on Cancer Risk", The Obesity Society, San Antonio, Texas, September 2012
114. "Dietary Weight Loss and Exercise Effects on Metabolic Hormones in Postmenopausal Women", Fred

- Hutchinson Cancer Research Center Symposium on Metabolism and Cancer, September 2012
115. ***"Lifestyle Modifications to Reduce Cancer Risk and Improve Overall Health", Global Summit on International Breast Health, Vienna, Austria, October 2012
 116. ***" Medical Perspective on the Influential Role of Obesity in the Risk and Prognosis of Breast Cancer" and "Obesity, chronic diseases and cancer, a common link with lifestyle" Mexican Association of Mastology, Villahermosa, Tabasco, Mexico, October 2012
 117. "Effects of Weight Loss and Physical Activity on Cancer Risk Factors: Evidence from Randomized Trials" Oregon Health Sciences University, October 2012
 118. "Weight Loss and Exercise" School of Breast Oncology, Atlanta GA, November 2012
 119. "Dietary weight loss and exercise effects on metabolic and sex hormones in postmenopausal women." American Association for Cancer Research, Washington, DC, April 2013
 120. "Obesity, Weight Loss, Vitamin D, and Cancer Biomarkers" Fred Hutchinson Cancer Research Center Joint Cancer Prevention/Epidemiology Seminar Series, May 2013
 121. ***"The WCRF/AICR Continuous Update Project – Systematic Reviews on Nutrition, Physical Activity & Health Outcomes in Cancer Survivors" International Union of Nutrition Scientists (IUNS) 20th International Congress of Nutrition, Granada, Spain, 2013
 122. ***"Appraisal of Evidence for Obesity Effects on Cancer" IASO/WCRF Obesity, Physical Activity and Cancer, London, 2013
 123. "Weight Loss & Exercise Effects on Breast Cancer Biomarkers" University of Illinois Symposium, Chicago, October 2013
 124. ***"Obesity, Physical Activity and Cancer" State Institute of Diabetes and Endocrinology & Catholic University Post Graduation course on Endocrinology and Metabolism. Rio de Janeiro, Brazil, October 2013
 125. "Weight Loss and Exercise" School of Breast Oncology, Atlanta GA, November 2013
 126. "Obesity, Physical Activity and Cancer" Keynote Speaker, The Center for Energy Balance in Cancer Prevention & Survivorship Research Retreat, MD Anderson Cancer Center, February 2014
 127. ***"Exercise in Cancer Prevention & Survivorship", Athens Institute for Education and Research, 10th Annual International Conference on Kinesiology and Exercise Sciences, Athens, Greece, August 2014
 128. ***"Weight Loss & Exercise Effects on Cancer Biomarkers," University of Tromso, Norway, September 2014
 129. "Breast Cancer Survivors: Findings from the Continuous Update Project," American Institute for Cancer Research Annual Conference, October, 2014.
 130. "Weight Loss and Exercise" School of Breast Oncology, Atlanta GA, November 2014
 131. "Obesity, Weight Loss, & Breast Cancer," University of Iowa Diabetes and Obesity Talks Seminar Series, November, 2014
 132. "Weight Loss & Exercise Effects on Breast Cancer Biomarkers," Memorial Sloan Kettering Cancer Center, New York, February, 2015.
 133. "Physical Activity & Weight Loss Effects on Cancer Biomarkers", NCI Schatzkin Talk, May 2015
 134. "Obesity, Weight Loss, Exercise & Breast Cancer" Seattle Cancer Care Alliance, May 2015
 135. ***"Associations of Weight, Physical Activity, & Diet with Breast Cancer Survival", International Society for Behavioral Nutrition & Physical Activity, Edinburg Scotland, June 2015
 136. "Weight Loss and Exercise" School of Breast Oncology, Atlanta GA, November 2015
 137. ***"The role of physical activity on cancer risk: epidemiology & molecular mechanisms" WCRF International and World Obesity Federation Joint Conference, September 2016
 138. ***"Anthropometry: What Can We Measure & What Does It Mean?" WCRF International and World Obesity Federation Joint Conference, September 2016
 139. ""Exercise, Weight, and Cancer Risk" University of Alabama Center for Exercise Medicine, Birmingham, September 2016
 140. ***"Long-term Effects of Exercise & Weight on Breast Cancer Biomarkers" University of Tromso, Norway, October 2016
 141. "Exercise, Weight, and Cancer Risk" Roswell Park Prevention Grand Rounds, Buffalo, NY, October 2016
 142. "Modifiable Health Behaviors for Cancer Survivors // Health Promotion: Exercise, Physical Rehab" SCCA Cancer Survivorship for Physicians CME, October 2016
 143. "Weight Loss and Exercise" School of Breast Oncology, Atlanta GA, November 2016

144. “Physical Activity & Cancer – What We Know, What We Don’t Know” American Institute for Cancer Research AICR’s 25th Research Conference, November 2016
145. ***“Screening for Breast Cancer: Pro”, EuroMedLab, Athens, Greece, June 2017
146. ***“Weight Control and Exercise for Breast Cancer Pts & Survivors”, Mexican Association of Mastology, 14th National Congress, Guadalajara – México, August, 2017
147. “Weight Loss and Exercise” School of Breast Oncology, Atlanta GA, November 2017
148. ***“Effects of Weight Loss on Cancer Biomarkers,” Canadian Cancer Research Conference, Vancouver, BC, Canada, November 2017
149. “Physical Activity and Diet for Cancer Prevention and Treatment: State of the Evidence,” Arizona State University, Tempe, Arizona, February, 2018
150. “Physical Activity for Cancer Prevention and Treatment: State of the Evidence,” Wolffe Lecture, American College of Sports Medicine, May 2018
151. ** Diet, Weight & Exercise in Cancer Prevention & Survival: the World Cancer Research Fund Report,” Oncology Grand Rounds, BC Cancer, Vancouver, BC, Canada, September 2018
152. ***“Physical Activity and Cancer Prevention,” National Center for Sport and Exercise Medicine, University of Loughborough, England, July 2018
153. “Weight Control and Exercise for Breast Cancer Prevention,” National Cancer Institute, Stars in Nutrition and Cancer lecture, October, 2018

** International Presentations

FUNDED RESEARCH PROJECTS (total dollars unless otherwise noted)

Completed

- A Case-Control Study of Thyroid Cancer in Women, **PI: Anne McTiernan**, American Cancer Society Institutional Grant 1N-26-U, 1979-1982.
- Counseling Strategies for Breast Cancer Risk, PI: Deborah Bowen, PhD, NIH Grant #HG/CA01190-01, 1994-97, \$654,409.00.
- Fenfluramine as an Adjunct to Smoking Cessation Therapy, PI: Deborah Bowen, PhD, NIH Grant #R29CA50858, 1990-94.
- Feasibility Study of an Exercise-Diet Program for Breast Cancer Patients, PI: Anne McTiernan, FHCRC Bid and Proposal funds, 1995-1996, \$10,000 (direct)
- Echocardiographic Follow-up to a Randomized Trial of Fenfluramine in Women Smokers, PI: Deborah Bowen, PhD, Wyeth Ayerst research contract, 1998, \$1,957,627.
- A Randomized Controlled Trial of Fat Reduction and Risk of Proliferative Forms of Benign Breast Disease, WHI Ancillary Study, PI: Tom Rohan, MD; **PI of FHCRC subcontract to U. Toronto: Anne McTiernan**, \$13,699.
- Effect of Exercise on Mammogram Densities, **PI: Anne McTiernan**, FHCRC Bid and Proposal funds, 1999-2000.
- SEER Special Studies RFP Interaction of Genetic Susceptibility and Hormonal Exposures in Breast Cancer Prognosis, **PI: Anne McTiernan**, 1999-2001, \$137,465.
- SEER Special Studies RFP Mammographic Breast Density and Breast Cancer Prognosis, **PI: Anne McTiernan**, 1999-2001, \$123,558.
- Genetic Risk Information for a Defined Populations, PI: Deborah Bowen, PhD, NIH grant #HG/CA1190-01, 1998-2001, \$1,143,890.
- Effect of Hormone Replacement Therapy on Mammographic Density, WHI Ancillary Study, PI: Barbara Hulka, MD, MPH; **PI of FHCRC subcontract to UNC Chapel Hill: Anne McTiernan**, 1998-2003, \$876,824.
- Effect of Exercise on Sex Hormones in Postmenopausal Women, **PI: Anne McTiernan**, NIH R01CA/AG69334-01A2, 1997-2003, \$1,562,811.
- Effect of Exercise on Immune Function in Postmenopausal Women: Supplement to Effect of Exercise on Sex Hormones in Postmenopausal Women, **PI: Anne McTiernan**, NIH R01CA/AG69334-01A2, 1998-2003, \$439,112.
- Women’s Intervention Nutrition Study (WINS) FHCRC Clinical Center, PI: Alan Kristal; Past-PI, \$28,400.
- Exercise Intervention Trial for Colorectal Polyp Patients, **PI: Anne McTiernan**, R01 CA77572-01, 2000-2007, \$4,046,212.

- Clinical Coordinating Center, Women's Health Initiative Trial & Observational Study, PI: Ross Prentice; **Role on project: Co-Investigator**, NIH N01-WH-2-2110, 1992-2007+, \$112,336,577.
- Randomized, Double-Blind, Placebo Controlled Trial of 4-OH Tamoxifen Gel in Premenopausal Women with 50-80% Density in Breast tissue Based on Digitized Analysis of Screening Mammography, Besins International U.S. Inc. **PI: Anne McTiernan**, 2002-2003, \$116,165.
- Seattle Cancer & Aging Program – Pilot: Effect of Exercise on Prostate Cancer Biomarkers: An Ancillary Study to a Randomized Controlled Clinical Trial, PI: Peter Rabinovitch; **PI of Pilot Study: Anne McTiernan**, P20 CA103728, 2004-2006, \$39,049.
- Study of Tamoxifen vs. Raloxifene (STAR), PI: R. Clarfeld; **Role on project: Co-Principal Investigator**.
- Exercise and Fitness in Childhood Cancer Survivors, PI: Debra Friedman; **PI of FHCRC Subcontract: Anne McTiernan**, NCI R21, 2004-2006, \$23,904 (direct).
- Proteomic Markers of Health Behaviors, PI: Paul Lampe/Yutaka Yasui; **Role on project: Co-Investigator**, NCI-5 R03 CA108339-02, 2004-2006, \$173,000.
- Randomized placebo-controlled biomarker modulation trial using Celecoxib in premenopausal women at high risk for breast cancer, SWOG, PI: Powell Brown; **PI of FHCRC subcontract: Anne McTiernan**, NIH/NCI CA37429, 2005-2006, \$37,799.
- Effects of Aspirin on Biomarkers of Breast Cancer Risk (Avon Progress for Patients Funds), PI: Nicole Urban; **Role on project: Project Leader, wrote proposal and directed trial**, 2004-2007, \$496,238.
- ALPHA Trial: Alberta Physical Activity and Breast Cancer Prevention Trial. Canadian Breast Cancer Research Initiative, PIs: Christine Friedenreich and Kerry Courneya; **Role on project: Co-Investigator**, 2002-2007, \$1,104,147.
- Mammographic Density and Invasive Breast Cancer, PI: Etta Pisano, **PI of FHCRC Subcontract: Anne McTiernan**, R01 CA105007-01, 2004-2007, \$50,524 (direct).
- Cognitive Effects of Aerobic Exercise for Adults with Impaired Glucose Tolerance: A Controlled Trial (American Diabetes Association), PI: Laura Baker; **Role on project: Co-Investigator**, 2004-2007.
- Cognitive Effects of Aerobic Exercise for Adults with Mild Cognitive Impairment: A Controlled Trial (Alzheimer's Association), PI: Laura Baker; **Role on project: Co-Investigator**, 2004-2007.
- Social and Physical Activity of Childhood Cancer Survivors, PI: Debra Friedman; **Role on project: Co-Investigator**, NIH/NCI CA 104123-01A2, 2005-2007, \$107,500.
- UW Multidisciplinary Research Training Grant, PI: R Deyo; **Role on project: Co-Investigator, Mentor**, 1 K12 HD 49100-01, 2004-2009, \$1,172,239.
- Epidemiology of Gallbladder Sludge and Stones in Pregnancy, PI: Sum Lee; **Role on project: Co-Investigator**, RO1 DK46890, 2003-2008, \$372,840.
- Breast Cancer Prognostic Factors/Pathobiology by Age, PI: Kathi Malone; **Role on project: Co-Investigator**, NCI-1 R01 CA098858-01A2, 2004-2009.
- Seattle TREC Center, **PI: Anne McTiernan**, NIH/NCI U54 CA116847, 09/23/2005 – 08/31/2011, \$12,612,045.
- Exercise, Diet, and Postmenopausal Sex Hormones, **PI: Anne McTiernan**, NIH/NCI R01 CA105204, 09/01/2004 – 06/30/2011, \$3,348,605.
- Reducing Obesity at the Workplace: A Randomized Trial, PI: Shirley Beresford; **Role on project: Co-Investigator**, NIH/NHLBI R01 HL079491, 7/1/2004-6/30/2011.
- Effect of Exercise and Weight Loss on Adipose Tissue Biology, **PI: Anne McTiernan**, NIH/NCI R21 CA131676, 05/01/2008 – 04/30/2011, \$435,600.
- Effect of Dietary Intervention on Insulin and IGF-1 Receptors in Prostate Cancer (Pacific NW Prostate SPORE pilot project), **PI: Anne McTiernan**, NIH/NCI P50 CA97186, 09/01/2009 – 08/31/2011, \$48,836.
- Alberta Physical Activity (ALPHA) and Breast Cancer Prevention Trial: an ancillary study examining androgens, biomarkers of obesity, and inflammation. Alberta Breast Cancer Research Initiative, PI: CM Friedenreich; **Role on project: Co-Investigator**, \$170,000.
- Bid & Proposal Funds to Assess Baseline Body Composition, by Dual X-ray Absorptiometry (DXA), in Participants of an Ongoing Clinical Trial (Vitamin D, Diet & Activity Study, ViDA) **PI: Anne McTiernan**, 12/1/2010 – 06/30/2011, \$16,000 (direct).
- A Phase III Randomized Controlled Study of Exemestane Versus Placebo in Postmenopausal Women at Increased

Risk of Developing Breast Cancer. **PI of FHCRC Clinic: Anne McTiernan**, National Cancer Institute of Canada, 10/2004 – 11/2012, \$1,631,150.

- Komen Scientific Advisory Council Award “Vitamin D, Weight Loss, and Breast Cancer Biomarker,” **PI: Anne McTiernan**, SAC110024, 07/01/2010 – 06/30/2012, \$500,000.
- Weight Loss & Exercise Effects on Telomere Length in Postmenopausal Women, **PI: Anne McTiernan**, NIH/NCI R21 CA155823, 12/14/10 – 11/30/12, \$428,705.
- Oxidative Stress in Chronic Kidney Disease, University of UW PI: Jonathan Himmelfarb; **Role on project: PI of FHCRC subcontract**, NIH/NHLBI R01 HL070938, 01/01/2011 – 12/31/2012, \$197,630 (FHCRC only).
- Komen Scientific Advisory Council Award “Vitamin D, Weight Loss, and Breast Cancer Biomarker,” **PI: Anne McTiernan**, SAC110024, 07/01/2012 – 06/30/2013, \$225,000.
- NCI: Exercise Effects on Serum Biomarkers of Angiogenesis, PI: Catherine Duggan, PhD; **Role on Project: Co-Investigator & Mentor**, NIH/NCI R03 CA152847, 04/01/2011 – 03/31/2013, \$176,000.
- HEAL Follow-up, NIH/NCI Contract. Manuscript Development for the HEAL Study of Breast Cancer Prognosis, **PI: Anne McTiernan**, NCI contract, 10/2012-9/2013
- Vitamin D Effect on Body Composition During Behavioral Weight Loss in Women, **PI: Anne McTiernan**, NIH 1R03CA162482, 04/01/12 – 03/31/14, \$175,000
- Effect of Vitamin D and Weight Loss on Biomarkers of Breast Cancer Risk, **PI: Anne McTiernan**, Breast Cancer Research Foundation, 10/1/13-9/30/14, \$230,378.
- Effect of Weight Loss & Exercise on Biomarkers of Breast Cancer Risk, **PI: Anne McTiernan**, Breast Cancer Research Foundation, 10/1/14-9/30/15, \$250,000.
- Weight Loss & Cancer Biomarkers in Women: Oxidative Stress & Inflammation, **PI: Anne McTiernan**, NIH/NCI, 1R01CA161131, 04/15/2012 – 9/30/2015, \$863,179.
- Safeway Foundation Assessing Vitamin D, Weight Loss and Breast Cancer Risk Factors, Safeway Foundation, PI: Catherine Duggan, PhD; **Role on Project: Co-Investigator & Mentor**, 7/1/2013 – 6/30/2014, \$36,000 (in NCE).
- Effect of Weight Loss & Exercise on Biomarkers of Breast Cancer Risk, **PI: Anne McTiernan**, Breast Cancer Research Foundation, 10/1/15-9/30/16, \$250,000.
- Effect of Weight Loss & Exercise on Biomarkers of Breast Cancer Risk, **PI: Anne McTiernan**, Breast Cancer Research Foundation, 10/1/16-9/30/17, \$250,000.
- Methods for Measurement Error in Physical Activity & Diet, PI: CY Wang; **Role on Project: Co-Investigator**, NIH/NHLBI R21HL121347, 12/1/13-12/31/16, \$494,493.

Active

- Effect of Weight Loss & Exercise on Biomarkers of Breast Cancer Risk, **PI: Anne McTiernan**, Breast Cancer Research Foundation, 10/1/17-9/30/18, \$250,000.
- Effect of Weight Loss & Exercise on Biomarkers of Breast Cancer Risk, **PI: Anne McTiernan**, Breast Cancer Research Foundation, 10/1/18-9/30/19, \$250,000.
- INTense Exercise foR surVivAL among men with Metastatic Castrate-Resistant Prostate Cancer (INTERVAL – MCRPC): A Multicenter, Randomized, Controlled, Phase III Study, PI: Jonathan Wright; **Role on Project: Co-Investigator**, November, 2016 - .
- Exercise Effects in Men & Women on Colon DNA Methylation, **PI: Anne McTiernan**, NIH/NCI 1R21CA209203-01A1, 3/15/17 – 2/28/19, \$421,080.
- Exercise Effects in Men & Women on Colon DNA Methylation, **PI: Anne McTiernan**, NIH/NCI 1R21CA209203-01A1, 3/15/17 – 2/28/19, Administrative supplement, \$176,000.
- Impact of an exercise program in cancer patients on chemotherapy treatment, **PI's: Anne McTiernan & Blair Irwin**, Ben Greer SCCA Pilot Study Funds, 9/17-8/18, \$50,000 (no cost extension).
- Longitudinal Weight Data from Two Behavioral Weight Loss Randomized Controlled Trial, **PI: Anne McTiernan**, FHCRC Bid & Proposal Funds, 10/17-9/18, \$15,000.
- The effects of moderate exercise on distress, quality of life, and biomarkers of angiogenesis and chronic stress in ovarian cancer survivors, NCI R21CA215662-01A1, PI: Kathryn Pennington; **Role on Project: Co-Investigator**

TEACHING/MENTORING

Junior Faculty

Katy Pennington, MD (School of Medicine, OB/GYN, University of Washington)
Holly Harris, PhD (Epidemiology Program, PHS, FHCRC)
Catherine Duggan, PhD (Epidemiology Program, PHS, FHCRC)
Blair Irwin, MD (Multi-Care, Tacoma, SCCA affiliate)
Jonathan Wright, MD, MPH (School of Medicine, Urology, University of Washington & Epidemiology Program, PHS, FHCRC)

Postdoctoral Fellows

1. Melinda Irwin, PhD (current Full Professor, Yale University)
2. Melanie Palomares, MD, MPH (current faculty City of Hope, Los Angeles)
3. Laura Frank, PhD
4. Page Abramson, PhD
5. Karen Foster-Schubert, MD (current Assistant Professor, U. of Washington)
6. Kristin Campbell, PhD (current Assistant Professor, U. British Columbia)
7. Lisa Cadmus, PhD (current staff scientist U. C. San Diego)
8. Ikuyo Imayama, MD (current medical resident, Seton Hall University, St. Francis Medical Center, Trenton, NJ)
9. Caitlin Mason, PhD (current postdoctoral fellow, FHCRC)

Additional Postdoctoral Fellows Working with My Studies' Data

10. Jean De Dieu Tapsoba, PhD (current postdoctoral fellow, FHCRC; primary mentor is CY Wang, PhD)
11. Aaron Thrift, PhD (current postdoctoral fellow, FHCRC; primary mentor is T. Vaughan, MD)

PhD Committees and Predoctoral Trainee Mentoring

1. Lisa Godefroy Johnson (member of PhD committee)
2. Shelley Slate Tworoger (member of PhD committee)
3. Cara Frankenfeld (member of PhD committee)
4. Victoria M. Chia (member of PhD committee)
5. Lori Williams (member of PhD committee)
6. Angela Kong (co-chair of PhD committee)
7. Babbette Saltzman (member of PhD committee)
8. Anita Iverson (visiting Norwegian predoctoral student 2009-10, advising)
9. Adriana Villasenor (member of PhD committee)
10. Sissi Espetvedt Finstad, MD (Norwegian PhD student, advising)

MS and MPH Committees

1. Margaret Krieg, MD (member of MPH committee)
2. Sylvia Young, MD (chair of MPH committee)
3. Jana Pruski (chair of MPH committee)
4. Melanie Palomares (chair of MPH committee)
5. Susan Stanford (member of MPH committee)
6. Melinda Irwin, PhD (chair of MPH committee)
7. Andrew Shors, MD (member of MPH committee)
8. Libbby Morimoto (member of M.S. committee)
9. Breanna Mitchell (member of M.S. committee)
10. Erin Aiello (chair of MPH committee)
11. Erin Shade (member of M.S. committee)
12. Julie Meyers (member of M.S. committee)
13. Manish Mohanka (chair of MPH committee)
14. Vivian Hawkins (chair of MPH committee)
15. Isaac Rhew (member of MPH committee)
16. Ann Ready (member of MPH committee)

17. Alanna Boynton (member of MS committee)
18. Heather Hildebrandt (member of MPH committee)
19. Jo Henderson (chair of MPH committee)
20. Laura Hooper (member of MPH committee)
21. Kristen Sipsma (member of MPH committee)
22. Karen Foster-Schubert (chair of MS committee)

Advising: Medical Students Research (University of Washington ISMS): Jennifer Rupert, Erin Griffith, Kelley D. Pratt, Maegan Ashworth

Post-Graduate Physician Training in Cancer Prevention & Control (FHCRC): Elliott Rosenberg, MD, MPH, Mary Ann Gilligan, MD, MPH, Maureen Brown, MD

Formal Career Development Mentoring: Karen Foster-Schubert, MD, University of Washington NIH K-12 Fellow 2005-2010; Karen Mustian, PhD University of Rochester NCI Cancer Control Clinical Research Training Program 2004-

FHCRC scientists mentoring: Neli Ulrich, PhD, Rebecca Rudolph, MD, MPH, AnneClaire DeRoos, PhD, Alyson Littman, PhD, Jonathan Wright, MD, MPH, Catherine Duggan, PhD, Larissa Korde, MD

Individual Study Credits

<u>Course</u>	<u>Title</u>	<u>Credits</u>	<u>Years</u>
Epi 499	Undergraduate Research	Var	1997-2005
Epi 600	Graduate Study/Research	Var	1997-2005
Epi 700	Masters Research	Var	1998-2005
Cancer Epi	guest lecture	1999, 2002-2005	

Continuing Medical Education Teaching

- Breast Cancer in Young Women, University of Washington Continuing Education Conference, August 6, 1994, Depts. of Surgery and Medicine.
- Current Concepts in the Early Detection of Breast Cancer, Multicare, Madigan Army Medical Center, and American Cancer Society 3rd Annual Oncology Conference, April 11, 1995.
- Current Concepts in Breast Cancer – 1997, University of Washington Continuing Medical Education, October, 1997, 1999, 2000 (session moderator), 2001, 2003, 2009, 2010
- “Update to the Women’s Health Initiative” March 18, 2001, University of Washington talk to IM, GYN, FM residents.

Clinical Teaching (U. of Washington School of Medicine)

- Attending Physician, Adult Medical Center, Harborview Medical Center, 1992-95 – supervised internal medicine residents in primary care setting.
- Mentoring and training geriatric fellow, Dr. Michi Yukawa, in exercise tolerance testing and testing VO2 max (1999)

Other Academic

Primary Opponent, PhD Thesis Defense, Aina Emaus, University of Oslo, Norway (thesis chair, Inger Thune) 2009

FHCRC SERVICE

- Director, Prevention Center Shared Resource, 2001-2012
- Chair or Member of several faculty promotion committees and 5-year review committees
- Reviewer for CCSG renewal: 2013, 2018
- Member, Scientific Advisory Committee for the Seattle Cancer Care Alliance Prevention Clinic
- Member, Research Trials Office Oversight Committee, 2003 – 2005
- Member, Fred Hutchinson Cancer Research Center Institutional Review Board, 1984-5; 2002 - 2003
- Member, FHCRC Health Care Task Force, 1996
- Member, Clinical Protocol Scientific Review and Monitoring Committee, 1996- 1997
- Organizer, FHCRC Public Health Sciences Hormone Special Interest Group 1995-96
- Member, Seattle Breast Cancer Program Executive Committee, 1998 - 2000
- Member, Ad-Hoc Committee on Improvements in Public Health Sciences Procedures, 1998
- Member, CSS Advisory Committee, 1999 – 2000

- Nutritional/Hormonal Biomarkers group, 2001 – 2002
- Member, CDS Users Group, 2001 – 2002

UNIVERSITY OF WASHINGTON SERVICE

- Reviewer, Royalty Research Fund, Spring, 1997
- U. Washington Breast Cancer Update 2000 Continuing Medical Education – session moderator

PROFESSIONALLY-RELATED COMMUNITY SERVICE

- Medical Advisory Board, Team Survivor Northwest 1997-
- Professional Advisory Committee, Breastcancer.org, 2003-

LAY AUDIENCE PRESENTATIONS

- National Council of Jewish Women, Seattle Section, “Women’s Health Initiative”, Nov 1992
- Nordstrom’s “Face of Breast Cancer” breast cancer awareness seminar, October 1997
- Danskin Women’s Triathlon, 8/15/98
- Afternoon of Hope, Horizon of Hope National Charity Campaign, Longaberger Co., FHCRC, 8/29/98
- Media roundtable, Women’s Health Initiative, December, 1995
- Breast Cancer Forum: Clinical Implications of Current Research, FHCRC, 10/8/98
- Women’s Health Issues Panel, The Healthy Living Expo, Seattle, WA, 2/7/99
- Virginia Mason Hospital Breast Cancer Support Group “Weight Control and Cancer Survival” September 1999.
- FHCRC Volunteer Conference “Breast Cancer Risk Factors” May 2000.
- FHCRC Women’s Health Series “Exercise and Breast Cancer” April 2000.
- Bellevue Rotary Club, “Exercise and Breast Cancer” October 2000.
- Cardio Pulmonary Rehabilitation Institute Oncology Rehabilitation, Lubbock Texas, “Exercise for Breast Cancer Prevention and Rehabilitation”, March 2001
- Greater Cincinnati Breast Cancer Association, October 2001.
- FHCRC Community Lecture "Exercise for Breast and Colon Cancer Prevention" November 2001
- Providence/St. Vincent Medical Center, Portland, OR October 2003
- Women’s Health Day, Anchorage, Alaska 2005
- Cancer Wellness Center, Northbrook, IL 2005

MEDIA

- Media (TV) interviews on physical activity, obesity, vitamin D, sleep, cancer: Today Show (NBC); MSNBC News Show; ABC News w/Peter Jennings; ABC World News Tonight; CBS Evening News; CBS News; Seattle KOMO, KIRO, KING, FOX13; WZTV-FOX, KOCO-ABC, WFLA-NBC, WBTB-CBS, WLAK-FOX
- Media (radio): KJZZ, Canadian health radio talk show; numerous Seattle-area radio interviews
- Media (print) –Prevention Magazine, American Health Magazine, Time Magazine, Parents’ Magazine, Family Circle, Associated Press, Time, Women’s World, Cosmopolitan, Glamour, Self, Reader’s Digest, New York Times, Wall Street Journal, LA Times, Parade Magazine, Seattle Times Pacific Magazine, USA Today, U.S. News and World Report, Health Magazine, Seattle Magazine, Self, More and others
- Several on-line news media each year
- “Preventing Breast Cancer” written commentary for ABC.com, April 2002.
- Ivanhoe National TV Productions specials on Breastfeeding, Breast Cancer, and Breast Gel Study September 2002

Exhibit 18

Anne McTiernan, Ph.D

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

)
IN RE: JOHNSON & JOHNSON TALCUM)
POWDER PRODUCTS MARKETING, SALES)
PRACTICES, AND PRODUCTS LIABILITY) MDL No. 2738 (FLW)(LHG)
LITIGATION)
)
)

VIDEOTAPED DEPOSITION OF ANNE MCTIERNAN, PH.D.

January 28, 2019

Seattle, Washington

Anne McTiernan, Ph.D

Page 2	Page 4
<p>1 APPEARANCES</p> <p>2 For Johnson & Johnson:</p> <p>3 Bart H. Williams, Esquire</p> <p>4 Susan Gutierrez, Esquire</p> <p>5 Proskauer Rose LLP</p> <p>6 2029 Century Park East</p> <p>7 Suite 2400</p> <p>8 Los Angeles, CA 90067-3010</p> <p>9 310.284.4520</p> <p>10 310.557.2193 Fax</p> <p>11 Bwilliams@proskauer.com</p> <p>12 sgutierrez@proskauer.com</p> <p>13 Benjamin S. Halperin, Esquire</p> <p>14 Skadden Arps Slate Meagher & Flom LLP</p> <p>15 4 Times Square</p> <p>16 New York, NY 10036</p> <p>17 212.735.2453</p> <p>18 917.777.2453 Fax</p> <p>19 Benjamin.halperin@skadden.com</p> <p>20 For Plaintiffs:</p> <p>21 Michelle A. Parfitt, Esquire</p> <p>22 Ashcraft & Gerel, LLP</p> <p>23 1825 K Street NW</p> <p>24 Suite 700</p> <p>25 Washington, D.C. 20006</p> <p>202.803.7077</p> <p>Mparfitt@ashcraftlaw.com</p> <p>Cynthia L. Garber, Esquire</p> <p>Robinson Calcagnie, Inc.</p> <p>19 Corporate Plaza Drive</p> <p>Newport Beach, CA 92660</p> <p>949.720.1288</p> <p>949.456.0037 Fax</p> <p>Cgarber@robinsonfirm.com</p> <p>Richard M. Golomb, Esquire</p> <p>Golomb & Honik, PC</p> <p>1835 Market Street</p> <p>Suite 2900</p> <p>Philadelphia, PA 19103</p> <p>215.985.9177</p> <p>215.985.4169 Fax</p> <p>rgolomb@golombhonik.com</p>	<p>1 EXAMINATION INDEX</p> <p>2 EXAMINATION BY: PAGE NO.</p> <p>3 MR. WILLIAMS 10</p> <p>4 MS. ERFLE 299</p> <p>5 MS. PARFITT 305</p> <p>6</p> <p>7 EXHIBIT INDEX</p> <p>8 EXHIBIT NO. DESCRIPTION PAGE NO.</p> <p>9</p> <p>10 Exhibit No. 1 Notice of oral and videotaped 15</p> <p>11 deposition of Anne McTiernan</p> <p>12 and duces tecum.</p> <p>13 Exhibit No. 1A Plaintiff's steering 21</p> <p>14 committee's response and</p> <p>15 objections to the notice of</p> <p>16 oral and videotaped</p> <p>17 deposition of Anne McTiernan</p> <p>18 and duces tecum.</p> <p>19 Exhibit No. 2 "Rule 26 expert report of 19</p> <p>20 Anne McTiernan, MD, PHD,"</p> <p>21 dated 11/16/18.</p> <p>22 Exhibit No. 3 "Additional materials to 63</p> <p>23 Dr. Anne McTiernan."</p> <p>24 Exhibit No. 4 World Cancer Research Fund 69</p> <p>25 and American Institute for</p> <p>Cancer Research, "Ovarian</p> <p>cancer 2014 report."</p> <p>Exhibit No. 5 World Cancer Research Fund 82</p> <p>and American Institute for</p> <p>Cancer Research, "Diet,</p> <p>nutrition, physical activity</p> <p>and ovarian cancer - Revised</p> <p>2018."</p>
Page 3	Page 5
<p>1 APPEARANCES (CONTINUED)</p> <p>2</p> <p>3 For Imerys:</p> <p>4 Nancy M. Erfle, Esquire</p> <p>5 Gordon & Rees Scully Mansukhani, LLP</p> <p>6 121 SW Morrison Street</p> <p>7 Suite 1575</p> <p>8 Portland, OR 97204</p> <p>9 503.222.1075</p> <p>10 503.616.3600 Fax</p> <p>11 Nerfle@grsm.com</p> <p>12 For PTI Union, LLC and PTI Royston:</p> <p>13 Michael Anderton, Esquire</p> <p>14 Tucker Ellis LLP</p> <p>15 950 Main Avenue</p> <p>16 Suite 1100</p> <p>17 Cleveland, Ohio 44113-7213</p> <p>18 216.696.4835</p> <p>19 216.592.5009 Fax</p> <p>20 Michael.anderton@tuckerellis.com</p> <p>21 For Personal Care Products Council:</p> <p>22 Thomas T. Locke, Esquire</p> <p>23 Seyfarth Shaw LLP</p> <p>24 975 F Street NW</p> <p>25 Washington, D.C. 20004-1454</p> <p>202.828.5376</p> <p>202.641.9276 Fax</p> <p>Tlocke@seyfarth.com</p> <p>Also present: Anthony Bocci, Videographer</p>	<p>1 EXHIBIT INDEX (CONTINUED)</p> <p>2</p> <p>3 Exhibit No. 6 World Cancer Research Fund 83</p> <p>4 International, CUP panel web</p> <p>5 page excerpt, "CUP expert</p> <p>6 panel."</p> <p>7 Exhibit No. 7 World Cancer Research Fund 98</p> <p>8 web page excerpt, "Myths and</p> <p>9 controversies about what</p> <p>10 causes cancer."</p> <p>11 Exhibit No. 8 American Institute for Cancer 103</p> <p>12 Research, "GMOs and other hot</p> <p>13 topics."</p> <p>14 Exhibit No. 9 Hutch News, "How to reduce 105</p> <p>15 the odds of getting cancer."</p> <p>16 Exhibit No. 10 World Cancer Research Fund 110</p> <p>17 and American Institute for</p> <p>18 Cancer Research, "Judging the</p> <p>19 evidence."</p> <p>20 Exhibit No. 11 "Language from CUP judging 138</p> <p>21 the evidence report quoted</p> <p>22 without citation in</p> <p>23 Dr. McTiernan's expert</p> <p>24 report."</p> <p>25 Exhibit No. 12 Article, "Information bias in 164</p> <p>epidemiological studies with</p> <p>a special focus on obstetrics</p> <p>and gynecology."</p> <p>Exhibit No. 13 Article, "Prospective study 167</p> <p>of talc use and ovarian</p> <p>cancer."</p> <p>Exhibit No. 14 Article, "Genital talc 169</p> <p>exposure and risk of ovarian</p> <p>cancer."</p> <p>Exhibit No. 15 Article, "Perineal talc use 180</p> <p>and ovarian cancer."</p>

Anne McTiernan, Ph.D

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<p>1 EXHIBIT INDEX (CONTINUED)</p> <p>2 Exhibit No. 16 Article, "Genital use of talc 192</p> <p>3 and risk of ovarian cancer: A</p> <p>4 meta-analysis."</p> <p>5 Exhibit No. 16A Article, "Genital use of talc 197</p> <p>6 and risk of ovarian cancer: A</p> <p>7 meta-analysis."</p> <p>8 Exhibit No. 17 Study, "Systematic review and 203</p> <p>9 meta-analysis of the</p> <p>10 association between perineal</p> <p>11 use of talc and risk of</p> <p>12 ovarian cancer."</p> <p>13 Exhibit No. 18 Article, "The relationship 232</p> <p>14 between perineal cosmetic</p> <p>15 talc usage and ovarian talc</p> <p>16 particle burden"</p> <p>17 Exhibit No. 19 Collection of tests from 260</p> <p>18 John Hopkins' deposition, his</p> <p>19 Exhibit No. 24.</p> <p>20 Exhibit No. 20 Collection of tests from 263</p> <p>21 John Hopkins' deposition, his</p> <p>22 Exhibit No. D-1, including</p> <p>23 "The whole story."</p> <p>24 Exhibit No. 21 "IARC monographs on the 274</p> <p>25 evaluation of carcinogenic</p> <p>risks to humans. Volume 93 -</p> <p>Carbon black, titanium</p> <p>dioxide, and talc;" Lyon,</p> <p>France, 2010.</p> <p>Exhibit No. 22 Article, "Perineal use of 279</p> <p>talc and risk of ovarian</p> <p>cancer."</p> <p>Exhibit No. 23 Testing document from 302</p> <p>Ms. Pier's deposition, Pier</p> <p>Exhibit No. 47.</p> <p>Exhibit No. 24 Copies of Dr. McTiernan's 303</p> <p>invoices to Ms. Parfitt.</p>	<p>1 BE IT REMEMBERED that on Monday,</p> <p>2 January 28, 2019, at 1301 Second Avenue, Suite 2000,</p> <p>3 Seattle, Washington, at 9:11 a.m., before Terilynn</p> <p>4 Simons, Certified Court Reporter, CCR, RMR, CRR, CLR,</p> <p>5 appeared ANNE MCTIERNAN, PH.D., the witness herein;</p> <p>6 WHEREUPON, the following proceedings</p> <p>7 were had, to wit:</p> <p>8</p> <p>9 <<<<<< >>>>>></p> <p>10</p> <p>11 VIDEOGRAPHER: We are now on the</p> <p>12 record. My name is Anthony Bocci. I am a videographer</p> <p>13 for Golkow Litigation Services. Today's date is</p> <p>14 1/28/2019, and the time is 9:11 a.m.</p> <p>15 This video deposition is being held at 1301 Second</p> <p>16 Avenue, Suite 2000, Seattle, Washington 98101 in the</p> <p>17 matter of In Re Johnson & Johnson Talcum Powder Products</p> <p>18 Marketing Sales Practices and Products Liability</p> <p>19 Litigation, for the United States District Court,</p> <p>20 District of New Jersey.</p> <p>21 The deponent is Dr. Anne McTiernan.</p> <p>22 Will Counsel please identify themselves for the</p> <p>23 record.</p> <p>24 MS. PARFITT: Good morning. Michelle</p> <p>25 Parfitt, counsel for the plaintiffs.</p>
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<p>1 EXHIBIT INDEX (CONTINUED)</p> <p>2</p> <p>3 Exhibit No. 25 Rule 26 expert report of Anne 304</p> <p>4 McTiernan, MD, PHD, dated</p> <p>5 November 16, 2018.</p> <p>6</p> <p>7 Exhibit No. 26 "Draft screening assessment," 306</p> <p>8 dated December 2018.</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 MS. GARBER: Good morning. Cynthia</p> <p>2 Garber on behalf of the plaintiffs.</p> <p>3 MR. GOLOMB: Richard Golomb on behalf</p> <p>4 of Plaintiffs.</p> <p>5 MS. ERFLE: Nancy Erfle on behalf of</p> <p>6 Imerys Talc America.</p> <p>7 MR. LOCKE: Tom Locke from Personal</p> <p>8 Care Products Council.</p> <p>9 MR. ANDERTON: Michael Anderton for</p> <p>10 PTI Royston, LLC and PTI Union, LLC.</p> <p>11 MR. HALPERIN: Benjamin Halperin for</p> <p>12 Johnson & Johnson.</p> <p>13 MS. GUTIERREZ: Susan Gutierrez for</p> <p>14 Johnson & Johnson.</p> <p>15 MR. WILLIAMS: And Bart Williams for</p> <p>16 Johnson & Johnson.</p> <p>17 VIDEOGRAPHER: Thank you.</p> <p>18 Will the court reporter now please swear in the</p> <p>19 witness.</p> <p>20</p> <p>21 ANNE MCTIERNAN, PH.D., having been first duly sworn</p> <p>22 by the Certified Court Reporter,</p> <p>23 testified as follows:</p> <p>24 ////</p> <p>25 ////</p>

3 (Pages 6 to 9)

Anne McTiernan, Ph.D

Page 10	Page 12
<p>1 EXAMINATION</p> <p>2 BY MR. WILLIAMS:</p> <p>3 Q Good morning, Dr. McTiernan.</p> <p>4 A Good morning.</p> <p>5 Q We just met this morning. My name is Bart Williams, and</p> <p>6 I represent Johnson & Johnson in this matter, which is</p> <p>7 pending in the District of New Jersey Federal Court.</p> <p>8 Are you aware of that?</p> <p>9 A Yes.</p> <p>10 Q Have you ever had your deposition taken before?</p> <p>11 A Never.</p> <p>12 Q The way this will work is I'll ask you questions.</p> <p>13 Counsel may interpose objections to my questions. There</p> <p>14 will be no judge here ruling on the objections, and after</p> <p>15 the objections, if any, you are supposed to answer the</p> <p>16 question.</p> <p>17 Do you understand that?</p> <p>18 A Yes.</p> <p>19 Q My understanding is that you have provided us with a USB</p> <p>20 drive; is that correct?</p> <p>21 A Michelle Parfitt provided you with that drive, yes.</p> <p>22 Q Are you aware of what's on that drive?</p> <p>23 A Yes. It's all the documents that I've used in forming my</p> <p>24 opinion.</p> <p>25 Q Are all of the files on the USB drive documents that you</p>	<p>1 MS. PARFITT: If I may, I am not sure</p> <p>2 that Dr. McTiernan knows that.</p> <p>3 The additional materials, they are not, to my</p> <p>4 knowledge, on that thumb drive.</p> <p>5 It was a list of some additional materials. I'm not</p> <p>6 sure that she's reviewed them all, and please feel free</p> <p>7 to make that inquiry, if you will, but I don't believe,</p> <p>8 Mr. Williams, they may be included on that thumb drive.</p> <p>9 That thumb drive should include the report, the</p> <p>10 references to the report.</p> <p>11 MR. WILLIAMS: Okay.</p> <p>12 Q (By Mr. Williams) Dr. McTiernan, when were you first</p> <p>13 approached about any involvement in talcum powder</p> <p>14 litigation?</p> <p>15 A It should have been 2016.</p> <p>16 Q And by whom were you approached?</p> <p>17 A By Ms. Parfitt.</p> <p>18 Q Michelle Parfitt, counsel who is--</p> <p>19 A Yes.</p> <p>20 Q One thing I should have told you, in order for the court</p> <p>21 reporter to take down everything that is said, you need</p> <p>22 to wait until I'm completely finished--</p> <p>23 A Oh, sorry.</p> <p>24 Q --with my question.</p> <p>25 You should take a pause and then answer the</p>
Page 11	Page 13
<p>1 considered in connection with your opinions in this case?</p> <p>2 A Yes.</p> <p>3 Q Are there any other files on the USB drive?</p> <p>4 A Not to my knowledge there are no other files.</p> <p>5 Q Can you be a little bit more particular about what types</p> <p>6 of documents, categories of documents, are contained on</p> <p>7 the drive?</p> <p>8 A So these will be scientific manuscripts published in</p> <p>9 peer-reviewed journals.</p> <p>10 They will be some expert testimony.</p> <p>11 There was government reports, and I don't have the</p> <p>12 full list right in front of me, so there are hundreds of</p> <p>13 these things, but in general classifications, I think</p> <p>14 that is-- that covers it generally.</p> <p>15 Q Those are all the things you recall at this time?</p> <p>16 A That's what I recall.</p> <p>17 My report should be on there as well, my CV, and</p> <p>18 government reports of-- other expert reports-- if I</p> <p>19 mentioned that.</p> <p>20 Q Let me stop you there.</p> <p>21 A Yeah.</p> <p>22 Q Does the USB drive contain all of the materials that were</p> <p>23 just recently produced to the defense in the case a few</p> <p>24 days ago, which were entitled, "Additional materials"</p> <p>25 that you had reviewed?</p>	<p>1 question, okay?</p> <p>2 A Mm-hm, okay.</p> <p>3 Q Otherwise, she has to cut off part of the question, write</p> <p>4 down your partial answer, and then the rest of my</p> <p>5 question.</p> <p>6 Do you understand that?</p> <p>7 A Okay, yes.</p> <p>8 Q So the first person who approached you was Michelle</p> <p>9 Parfitt?</p> <p>10 A Yes.</p> <p>11 Q Do you remember--</p> <p>12 A For this-- yes, for this litigation, yes.</p> <p>13 Q When in 2016 did Ms. Parfitt approach you?</p> <p>14 A I don't have that in my head.</p> <p>15 We should have a record of that first interaction.</p> <p>16 Q I will just get your memory for now.</p> <p>17 Was it winter, spring, summer or fall?</p> <p>18 A It would be late summer.</p> <p>19 Q Did Ms. Parfitt contact you at your place of business?</p> <p>20 A She approached me first by an e-mail at my institutional</p> <p>21 e-mail address, yes.</p> <p>22 Q And what is that e-mail address?</p> <p>23 A At that time it was probably still amctiern@fhcrc.</p> <p>24 My institution has changed the middle part to</p> <p>25 FredHutch, so I believe she did the first one.</p>

4 (Pages 10 to 13)

Anne McTiernan, Ph.D

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<p>1 Either one goes to the same place.</p> <p>2 Q Have you known Ms. Parfitt or any of the other</p> <p>3 plaintiffs' lawyers prior to their contacting you?</p> <p>4 A No, I did not.</p> <p>5 Q How long after Ms. Parfitt first contacted you did you</p> <p>6 agree to work with them in connection with the talcum</p> <p>7 powder litigation?</p> <p>8 A It was approximately two months, and my institution</p> <p>9 requires that I get permission for doing such consulting,</p> <p>10 so the process took approximately two months before I</p> <p>11 received approval.</p> <p>12 Q As of late summer 2016, when Ms. Parfitt first contacted</p> <p>13 you, what institution are you talking about?</p> <p>14 A Oh, so Fred Hutch Cancer Research Center in Seattle.</p> <p>15 Q And if it took two months, that would mean that it was</p> <p>16 late summer, early fall when you had received approval;</p> <p>17 is that correct?</p> <p>18 A I believe, yes.</p> <p>19 Q And that's late summer, early fall of 2016, right?</p> <p>20 A I believe, yes.</p> <p>21 Q How much per hour are you billing for the literature</p> <p>22 review and preparation for your report in this matter?</p> <p>23 A That was \$450 an hour.</p> <p>24 Q At what rate are you charging for your time spent</p> <p>25 providing deposition testimony?</p>	<p>1 A Yes.</p> <p>2 Q When did you first see this?</p> <p>3 A Approximately a month ago.</p> <p>4 Q In response to this deposition notice, which lists</p> <p>5 certain categories of documents, have you brought any</p> <p>6 documents with you here today?</p> <p>7 A We have documents for reports that were available only</p> <p>8 recently, so too recent to have them on the thumb drive,</p> <p>9 so these include the Health Canada report, weight of</p> <p>10 evidence, the screening-- the draft screening assessment,</p> <p>11 risk management scope, information sheet, key messages,</p> <p>12 and a "Draft systematic review of meta-analysis" by</p> <p>13 Taher, so it's a signed manuscript.</p> <p>14 Q Anything else?</p> <p>15 A These others are all in my list of documents. These are</p> <p>16 just copies of them.</p> <p>17 Q So just let me clear that up.</p> <p>18 You have just mentioned that there are some reports</p> <p>19 in--</p> <p>20 A The Health Canada report.</p> <p>21 Q Let me just take them one at a time.</p> <p>22 A I'm sorry.</p> <p>23 Q You listed the Health Canada report, correct?</p> <p>24 A Yes.</p> <p>25 Q Something called the draft screening assessment?</p>
Page 15	Page 17
<p>1 A \$650.</p> <p>2 Q Is that the same amount that you would charge for hearing</p> <p>3 testimony if you were to testify at the Daubert, and</p> <p>4 that's D-A-U-B-E-R-T, hearing in the summer of 2019?</p> <p>5 A Yes.</p> <p>6 Q Do you charge for travel related to your work as an</p> <p>7 expert witness, separate and apart from any work that you</p> <p>8 may do while traveling?</p> <p>9 A I have not previously been an expert witness, so I can't</p> <p>10 give you an answer on what I usually do.</p> <p>11 Q So this is the very first time in your career where you</p> <p>12 have served as an expert witness; is that correct?</p> <p>13 A That's right.</p> <p>14 (Exhibit No. 1 marked</p> <p>15 for identification.)</p> <p>16</p> <p>17 Q (By Mr. Williams) We have marked as Deposition Exhibit</p> <p>18 No. 1 the deposition notice, and we will hand that out to</p> <p>19 you through your counsel.</p> <p>20 MS. PARFITT: I believe you have that,</p> <p>21 Anthony, the first notice.</p> <p>22 Q (By Mr. Williams) Do you have Exhibit No. 1, the</p> <p>23 deposition notice, in front of you?</p> <p>24 A Yes.</p> <p>25 Q Is this something you have seen before?</p>	<p>1 A So these are all part of the Health Canada report.</p> <p>2 These are the components of it.</p> <p>3 A screening assessment document, weight of evidence</p> <p>4 document, a document called "Risk management scope," one</p> <p>5 called-- the title is, "Talc - potential risk of lung</p> <p>6 effects and ovarian cancer." I am calling it key</p> <p>7 messages because that's the first title underneath that.</p> <p>8 There's a talc information sheet.</p> <p>9 And a government of Canada talc sheet.</p> <p>10 It looks like it's a public messages sheet.</p> <p>11 The last thing is a systematic review of</p> <p>12 meta-analysis of the association between perineal use of</p> <p>13 talc and risk of ovarian cancer by Taher, et al.</p> <p>14 Q And let me ask you to go a little bit more slowly when</p> <p>15 you read today so that the court reporter can get it</p> <p>16 down.</p> <p>17 Is that okay with you?</p> <p>18 A Yes.</p> <p>19 Q Is it accurate to say that the items you have just listed</p> <p>20 were not in your possession at the time that you prepared</p> <p>21 your report that has been provided in this case?</p> <p>22 A That is correct.</p> <p>23 They were published after that period.</p> <p>24 Q Is it accurate to say that none of the materials that you</p> <p>25 have in front of you now were able to inform the opinions</p>

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<p style="text-align: right;">Page 18</p> <p>1 that you expressed in the report, which predated your 2 receipt of those materials?</p> <p>3 A The Health Canada report, that is true for. 4 However, the other documents that I have here, one 5 is a paper that I cited from Blount. 6 One is information from the FDA website, which is-- 7 I was able to access before doing my report. 8 Then the last thing is-- I'm sorry, it's a 9 deposition of Dr. Blount held last April, so I had access 10 to that earlier as well.</p> <p>11 Q Let's do this, we previously went through a list of 12 materials, most of which related to the Health Canada 13 report. 14 Do you remember that?</p> <p>15 A Yes.</p> <p>16 Q Other than that set of materials that you previously 17 described, is everything in the blue folder that's in 18 front of you, that you have brought with you today, a 19 duplicate of another report that has already been 20 produced to us?</p> <p>21 A Yes. 22 There was also one list here of additional 23 materials, so that should have been-- additional 24 materials to Dr. McTiernan, and that should be in your 25 list of what you have as well.</p>	<p style="text-align: right;">Page 20</p> <p>1 Q We will take a look at that during a break and perhaps 2 get a copy of it.</p> <p>3 A Okay.</p> <p>4 Q When were the notes that you have written on your expert 5 report written on the report?</p> <p>6 A In the past week. 7 I realized, as I was reviewing and preparing, that I 8 had not used a program that would give the full name of 9 the references, so to aid in my review, I wrote in the 10 first author of the documents, the manuscripts that I was 11 referring to. 12 Everything listed here is-- that I've written is the 13 first author of an article, and then I've also underlined 14 a few places to jog my memory.</p> <p>15 Q Other than what you've just described, are there any 16 other notations that appear on the report document?</p> <p>17 A No, not to my knowledge, no.</p> <p>18 Q Did you bring with you today any invoices reflecting 19 statements that you have given to plaintiffs' counsel for 20 payment?</p> <p>21 A I did not bring them myself, but I believe you have them. 22 MS. PARFITT: We did-- we have them. 23 If we can just take a look at them-- they were just 24 sent this morning to us, to my office, so if I could have 25 a chance to look through them, and maybe after the break</p>
<p style="text-align: right;">Page 19</p> <p>1 Q We are going to mark a copy of that additional materials 2 list in a moment, but for now, is it accurate that at the 3 time that you prepared your report in this case, which 4 was submitted to us in November of 2018, you had not 5 reviewed the additional materials list materials that you 6 have just pointed to?</p> <p>7 A That is correct. 8 Those were not available at that time.</p> <p>9 Q Let's mark as Exhibit No. 2 to the deposition a copy of 10 your expert report from November of 2018. 11 I think your counsel already has that. 12 (Exhibit No. 2 marked 13 for identification.)</p> <p>14</p> <p>15 Q (By Mr. Williams) Is the document marked Exhibit No. 2 a 16 copy of the expert report that you prepared in this case?</p> <p>17 A Yes, it is.</p> <p>18 Q It's dated November 16th, 2018?</p> <p>19 A Yes.</p> <p>20 Q You have a copy of that report in front of you that you 21 are holding right now; is that right?</p> <p>22 A Yes.</p> <p>23 Q Does the copy that you are holding right now have notes 24 on it?</p> <p>25 A Yes, it does.</p>	<p style="text-align: right;">Page 21</p> <p>1 we can get them marked. 2 Would that be appropriate?</p> <p>3 MR. WILLIAMS: That's fine.</p> <p>4 MS. PARFITT: The only other thing I 5 ask, Mr. Williams, could we perhaps note the Exhibit 1A, 6 the objection to the notice of depo?</p> <p>7 MR. WILLIAMS: Sure.</p> <p>8 MS. PARFITT: Thank you. 9 (Exhibit No. 1A marked 10 for identification.)</p> <p>11</p> <p>12 Q (By Mr. Williams) Your counsel-- we have premarked as 13 Exhibit No. 1A the objections that were served by 14 Plaintiffs' counsel to the deposition notice that we 15 provided. 16 Have you seen that before?</p> <p>17 It's in front of you now.</p> <p>18 A This, no, I have not.</p> <p>19 Q So you have never seen the objections?</p> <p>20 A No, I have not.</p> <p>21 Q Did counsel consult with you at all at the time that was 22 prepared?</p> <p>23 A No.</p> <p>24 Q Let's go back to the point in time when you first spoke 25 with plaintiffs' counsel.</p>

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<p style="text-align: right;">Page 22</p> <p>1 You said Ms. Parfitt reached out to you by e-mail at 2 your institution, which was the Fred Hutch Institution; 3 is that right? 4 A Yes. 5 Q Was anyone else on the phone? 6 A No. 7 Q How long was that call? 8 A I don't remember. 9 I think it was brief, but I don't remember. 10 Q And you said "I think" that it took a few months for the 11 process at your institution to be completed; is that 12 right? 13 A Yes. 14 Q How long after that first approach by Ms. Parfitt in the 15 summer, late summer, of 2016 did you decide that you 16 would in fact want to serve as an expert in this matter? 17 A I decided within a week that I would be interested, but I 18 am required to do this process at my institution which 19 involves informing my division director and the senior 20 vice presidents of the institution as well as the 21 president, and in aiding that, our legal counsel reviews 22 all of these requests to do such consulting. 23 So that process happened to take a while. 24 This time, I'm not sure. I think somebody was on 25 vacation, so that's why it took two months, so during--</p>	<p style="text-align: right;">Page 24</p> <p>1 Q When you say you did preliminary searches on Medline, can 2 you recall any articles that you came up with? 3 A I previously had already reviewed for the New York 4 Times-- when they contacted me about my scientific 5 opinion or my clinical opinion of this matter, I had been 6 given two of the cohort study papers, one by Gertig, et 7 al., and one by Houghton, et al., and so I briefly 8 reviewed those, and-- as well as the Terry case-control 9 study in order to talk with the New York Times, so I knew 10 about those papers. 11 In the epidemiology field, we often see things over 12 time. 13 This has been something that has been studied for 14 quite a few years, so I've been aware of the issue but 15 have not done a systematic review and not done a causal 16 analysis, was not a focus of my research at that point. 17 Q At the time that you agreed to participate as an expert 18 in this litigation, is it accurate to say that the 19 studies that you had reviewed included the Terry 2013 20 analysis, the Gertig cohort study, the Houghton cohort 21 study, you had reviewed as all those things before you 22 decided to participate; is that true? 23 A I had read those, yes. 24 Q And you can't remember anything else, as you sit here 25 right now, that you had reviewed before you made that</p>
<p style="text-align: right;">Page 23</p> <p>1 in order to start the process, I had to be interested in 2 doing this, so that's why I did it, but I couldn't firmly 3 say I could do it until they gave me approval. 4 Q In that week's period of time, between the time 5 Ms. Parfitt first contacted you and the time that you 6 made the decision to participate in this litigation as an 7 expert, what, if any, documents relating to talcum powder 8 and ovarian cancer did you review? 9 A I had already known some of the literature, some of the-- 10 for example, the pooled analysis by Terry, et al., I had 11 already reviewed that in the past, and I think I did some 12 preliminary searches through Medline to see what the 13 available data were, but I did not do a systematic 14 review. 15 I was not able to share that with the counsel, who 16 was Ms. Parfitt at this point, because I wasn't able to 17 officially consult, but I was curious. I wanted to know 18 what the data was looking like, what papers were 19 available. 20 Q Other than the Terry 2013 article that you mentioned and 21 some preliminary searches that you did on Medline, is 22 there anything else you did in that week's period of 23 time? 24 A In that week? I don't recall anything else in that 25 period.</p>	<p style="text-align: right;">Page 25</p> <p>1 decision? 2 A I can't remember others. 3 Q Were there others or not? 4 A I can't remember. 5 I believe that I only looked at those two cohort 6 studies and the Terry pooled analysis. 7 Q Let me ask you to focus on Exhibit No. 2, your report. 8 Do you have that in front of you? 9 A Yes. 10 Q Does that report contain all of the opinions that you 11 intend to offer at any hearing on this matter? 12 A Yes, unless-- so you are talking about any future-- any 13 future questioning I face in the court? 14 If there's more research that is published by that 15 time, I would want to know about it to see if it affects 16 my opinion or what the research is. 17 As a scientist I would want to keep up to date, but 18 for right now, this is my scientific opinion, what's in 19 this report. 20 Q Today is my opportunity to ask you questions about your 21 opinions in this matter. 22 You understand that, right? 23 A Yes. 24 Q Have you modified your opinions in this litigation beyond 25 the opinions set forth in Exhibit No. 2?</p>

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<p>1 A No, I have not.</p> <p>2 Q Are there any few or additional opinions that you expect</p> <p>3 to testify to at any hearing in this matter, other than</p> <p>4 what is contained in your report, Exhibit No. 2?</p> <p>5 A Nothing that I foresee, that I expect.</p> <p>6 Q Did you personally type the report that's marked as</p> <p>7 Exhibit No. 2?</p> <p>8 A Yes, I did.</p> <p>9 Q Did anyone assist you in the preparation of your report?</p> <p>10 A The only assistance I had was occasionally if I couldn't</p> <p>11 get a paper myself, through my own institutional library,</p> <p>12 then we have an administrative assistant that I can ask</p> <p>13 for that, and I believe I asked for a couple of papers</p> <p>14 through that source.</p> <p>15 There were a couple of times when I asked</p> <p>16 Ms. Parfitt's firm if they had a paper. This was quite a</p> <p>17 few months after that period, perhaps half a year or</p> <p>18 longer by the time I asked them.</p> <p>19 Q When did you start drafting the litigation report marked</p> <p>20 as Exhibit No. 2?</p> <p>21 A That would have been winter of 2016 to spring of 2017.</p> <p>22 Q Since you typed the report yourself, am I right that you</p> <p>23 have a file of it either at home or on your office</p> <p>24 computer?</p> <p>25 A Yes, on my home computer.</p>	<p>1 was given approval to work on this, so anything I read</p> <p>2 before that, I did not charge my time.</p> <p>3 Q (By Mr. Williams) Is it accurate to say that the 240</p> <p>4 hours reflects all of the hours, through today, that you</p> <p>5 have spent on this matter?</p> <p>6 A Yes.</p> <p>7 Q And you broke it down to 211 hours through December 2018</p> <p>8 and another 25 hours since that time, correct?</p> <p>9 A Approximately 25 since that time, yeah.</p> <p>10 Q Let me ask you to look at your report and refer you to</p> <p>11 Pages 78 through 84.</p> <p>12 You identify 127 documents or other materials as</p> <p>13 references, correct?</p> <p>14 A Yes.</p> <p>15 Q Are those the materials that you are relying on to form</p> <p>16 the basis of your opinions in this case?</p> <p>17 A Yes, although there are different materials that I was</p> <p>18 able to review after the report was done, and they help</p> <p>19 support my opinion.</p> <p>20 Q And are those additional materials, materials that we</p> <p>21 have already discussed this morning?</p> <p>22 A Yes.</p> <p>23 Q Did the Plaintiffs' lawyers provide you with any of the</p> <p>24 references that are contained in Nos. 1 through 127?</p> <p>25 A I believe some of them they provided if it was one that I</p>
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<p>1 Q From start to finish did you work in the same file to</p> <p>2 draft this report or did you have different files or</p> <p>3 drafts?</p> <p>4 A I copied different drafts as a way of backing up.</p> <p>5 Q Have you maintained the drafts, the iterations, as it</p> <p>6 went along?</p> <p>7 A Yes.</p> <p>8 Q How many hours would you say you have spent preparing the</p> <p>9 litigation report since the winter of 2016 to the spring</p> <p>10 of 2017 when you started writing it?</p> <p>11 A I would say approximately 240 hours.</p> <p>12 Q And on what do you base that estimate?</p> <p>13 A On invoices that I submitted through December 2018, plus</p> <p>14 an additional 25 hours since that time.</p> <p>15 Q I take it from your last answer, that up through December</p> <p>16 2018 you billed 240 hours total; is that accurate?</p> <p>17 A No.</p> <p>18 As of December 2018 I believe it was 211 hours.</p> <p>19 Q And is that 211 hours the total amount of time that you</p> <p>20 have spent grappling with the issues in this litigation</p> <p>21 or is that just the time that you have spent writing the</p> <p>22 report?</p> <p>23 MS. PARFITT: Objection; form.</p> <p>24 You may answer.</p> <p>25 THE WITNESS: It was since the time I</p>	<p>1 couldn't obtain on my own.</p> <p>2 A few of the mechanistic studies, I believe.</p> <p>3 Q If you can identify them by number, that would be good.</p> <p>4 A Yeah.</p> <p>5 Well, certainly some of the depositions I had no-- I</p> <p>6 did not access myself, so No. 77, 78, 79.</p> <p>7 The Longo reports, so 79 through 83.</p> <p>8 84 as well they provided.</p> <p>9 Q Anything else?</p> <p>10 A I am trying to search.</p> <p>11 They sent me some of the IARC monographs, but I had</p> <p>12 access previously to them myself, so I'm not sure which</p> <p>13 way you would want to count that, if I accessed the IARC</p> <p>14 myself online, but that-- Ms. Parfitt also sent their</p> <p>15 copy of it, so from two sources I had the same things.</p> <p>16 These are the IARC monographs, "The evaluation of</p> <p>17 carcinogenic effects," No. 40 and 42.</p> <p>18 I think there was a third IARC report.</p> <p>19 Q Would that be No. 74?</p> <p>20 A Yes.</p> <p>21 Q Other than items 40, 42, 74, and 75 through 84, are there</p> <p>22 any other materials that were provided to you by</p> <p>23 plaintiffs' counsel?</p> <p>24 A I am searching here.</p> <p>25 Some of the mechanistic studies they were able to</p>

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<p>1 provide when I couldn't get them myself, and some of</p> <p>2 these journals were journals that were difficult to get,</p> <p>3 so I believe 85 and 90.</p> <p>4 Q Had you identified Items 85 and 90 prior to the time they</p> <p>5 were provided to you or did Counsel simply provide them</p> <p>6 to you?</p> <p>7 A No, I don't think they-- no, they didn't simply provide</p> <p>8 them to me.</p> <p>9 At the time that I added these, these were added</p> <p>10 toward the end of the time that I was preparing the</p> <p>11 report.</p> <p>12 I was able to see some other expert reports. One</p> <p>13 was a gynecologist -- I believe it was Plunkett -- who</p> <p>14 mentioned that there were-- that-- the issue of</p> <p>15 transporting had some additional references that I did</p> <p>16 not have.</p> <p>17 I had, originally, some mechanism-related papers</p> <p>18 related to migration of talcum powder products through</p> <p>19 the vaginal tract, and I didn't-- there were some</p> <p>20 additional ones here that I had not known about.</p> <p>21 I believe Egli and Sjosten were two-- sorry, 85 and</p> <p>22 90.</p> <p>23 Q References 77 through 84 appear to be deposition</p> <p>24 transcript exhibits and expert reports in litigation.</p> <p>25 Do you see that?</p>	<p>1 A Yes.</p> <p>2 Q Have you read all of those items?</p> <p>3 A Not in full.</p> <p>4 Do you want me to go through them one at a time?</p> <p>5 Q Let me just ask you generally, what's the difference</p> <p>6 between the references to your report and the items</p> <p>7 listed as additional materials and data considered? Why</p> <p>8 did you spread them out like that?</p> <p>9 A These up to 127 were available at the time that I was</p> <p>10 actively writing my report.</p> <p>11 Some of these other documents came along later and</p> <p>12 were available to me, so the counsel did provide them.</p> <p>13 Some of them were-- some of them were earlier, these</p> <p>14 Fletcher papers on-- on some of the mechanistic work was</p> <p>15 done earlier.</p> <p>16 Many of these are-- to my knowledge they were</p> <p>17 exhibits that were available from the case from the law</p> <p>18 firm.</p> <p>19 One of these is a repeat. 38 was listed originally.</p> <p>20 I think there's a little bit of variability here.</p> <p>21 Q Let me stop you there for a moment.</p> <p>22 A Yes.</p> <p>23 Q Did you read each of the 113 items in their entirety?</p> <p>24 A No, I did not.</p> <p>25 Q In describing the difference between the additional</p>
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<p>1 A Yes.</p> <p>2 Q Have you reviewed all of those transcripts?</p> <p>3 A I skimmed 77 and 78 and looked at some of the exhibits</p> <p>4 that they had with them.</p> <p>5 I skimmed Longo, but I read through the November</p> <p>6 and-- this is another one-- these are not dated here-- of</p> <p>7 February and November.</p> <p>8 Q Let's take them one at a time on Longo.</p> <p>9 No. 79 says Longo, Rigler, April 2017.</p> <p>10 Did you review that?</p> <p>11 A Only skimming that.</p> <p>12 For all of these, I looked at the summary in the</p> <p>13 beginning, which presented the numbers of samples that</p> <p>14 were tested and the numbers that were considered to have</p> <p>15 asbestos.</p> <p>16 Q So you only reviewed the summaries; is that accurate?</p> <p>17 A Summaries, yes.</p> <p>18 Q And that applies to 77 through 83?</p> <p>19 A Through 83, yes.</p> <p>20 Q Take a look at Page 84 of your litigation report.</p> <p>21 Do you have that in front of you?</p> <p>22 A Yes.</p> <p>23 Q It lists here, "Additional materials and data</p> <p>24 considered," and it lists thereafter 113 items.</p> <p>25 Do you see that?</p>	<p>1 materials and data considered and the 127 references that</p> <p>2 we've already gone over, is it accurate to say that the</p> <p>3 additional materials were all provided by plaintiffs'</p> <p>4 counsel?</p> <p>5 MS. PARFITT: Objection to form.</p> <p>6 THE WITNESS: It's not true.</p> <p>7 Some of these I had myself--</p> <p>8 Q (By Mr. Williams) Could you please identify all of the</p> <p>9 items on here, of the 113 items, that you had yourself</p> <p>10 prior to them being provided by plaintiffs' counsel?</p> <p>11 A Okay. No. 2, American Cancer Society, I accessed their</p> <p>12 website several times.</p> <p>13 31 is a Hartge paper on talc and ovarian cancer, so</p> <p>14 I accessed that myself.</p> <p>15 This isn't a Hartge paper title, so that's one</p> <p>16 problem, one reason I'm struggling here, so I assume that</p> <p>17 this is another review that she has written, Hartge, but</p> <p>18 I'm not sure if it's the same as the paper that I</p> <p>19 referenced as one of my case-control studies that are</p> <p>20 referenced.</p> <p>21 The same issue with 33, 34 because I did reference</p> <p>22 Henderson, these are migration papers, so I'm not sure</p> <p>23 about that.</p> <p>24 No. 37 I do consider. It was a subset of the other</p> <p>25 Huncharek review, so I did see this earlier. I just did</p>

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<p>1 not reference it for my report.</p> <p>2 38 is the same IARC monograph paper-- work that is</p> <p>3 referenced in the paper.</p> <p>4 Institute of Medicine I was not able to review.</p> <p>5 These other things look like they are Johnson &</p> <p>6 Johnson or-- no-- other industry documents.</p> <p>7 Q Let me stop you there for a moment.</p> <p>8 Remember, my question is simply:</p> <p>9 Of the 113 items, please just list the numbers that</p> <p>10 you had before they were provided by Plaintiffs' counsel.</p> <p>11 That's all I need.</p> <p>12 A Okay. Sorry.</p> <p>13 67 I had previously, 79, 80, 87, 88, 89, 90, 91.</p> <p>14 92 I believe I referenced earlier, so 92, 93, 94,</p> <p>15 100-- can you remind me, is this for-- to distinguish</p> <p>16 what was in my report or what I obtained on my own?</p> <p>17 Q What you obtained on your own.</p> <p>18 A Okay. 103 I obtained on my own.</p> <p>19 That's it.</p> <p>20 Q All of the items, other than those that you just listed,</p> <p>21 were provided to you by Plaintiffs' counsel, correct?</p> <p>22 A I believe so, yes.</p> <p>23 Q You did not read each and every page of the materials</p> <p>24 that were provided to you by Plaintiffs' counsel; is that</p> <p>25 true?</p>	<p>1 Q Is that how you phrased it, "what available evidence</p> <p>2 there was"?</p> <p>3 A As the questions came along of various-- of parts of</p> <p>4 data-- so this came up with a question of what other</p> <p>5 constituents are there in Johnson & Johnson Baby Powder</p> <p>6 and Shower to Shower, and I relied first on published</p> <p>7 data from Blount and Gordon, but I was interested in what</p> <p>8 other testing had been done to see what are the</p> <p>9 constituents, because otherwise there's no information,</p> <p>10 but it was a very general question. I didn't know what</p> <p>11 was available.</p> <p>12 Q In response to that question that you just described, the</p> <p>13 items that are listed here and the numbers that I just</p> <p>14 gave you, 40 through 47 for Imerys-- excuse me, 40</p> <p>15 through 46 for Imerys, and 47 through 65 for Johnson &</p> <p>16 Johnson, are the only documents that were provided to</p> <p>17 you?</p> <p>18 MS. PARFITT: Objection.</p> <p>19 THE WITNESS: For that, I would also</p> <p>20 have received Longo, but one issue is I don't know-- from</p> <p>21 looking at these numbers, I don't have them memorized</p> <p>22 what they are.</p> <p>23 I would have to look them up.</p> <p>24 I do know that the Longo reports are the results of</p> <p>25 testing of constituents of the products.</p>
Page 35	Page 37
<p>1 A I did not, that's true.</p> <p>2 Q Let me direct your attention to No. 47 through 65 on the</p> <p>3 list that begin with the letters JNJ.</p> <p>4 Do you see that?</p> <p>5 A Yes.</p> <p>6 Q Do you understand that these are internal Johnson &</p> <p>7 Johnson documents?</p> <p>8 Is that right?</p> <p>9 A I believe you.</p> <p>10 I don't know what they are from looking at just the</p> <p>11 numbers. I would have to reference back to my documents.</p> <p>12 Q No. 40 through 46 all start with the word Imerys,</p> <p>13 I-M-E-R-Y-S.</p> <p>14 Do you see those?</p> <p>15 A Yes.</p> <p>16 Q Do you understand those to be internal Imerys documents?</p> <p>17 A Again, I would have to look and see what they look like.</p> <p>18 Q Did you ask Plaintiffs' counsel to provide you with the</p> <p>19 Imerys and Johnson & Johnson documents?</p> <p>20 A No, I did not.</p> <p>21 Q So they just gave those to you?</p> <p>22 A I asked to see what available evidence there was, and</p> <p>23 the-- the evidence that had been collected for the case</p> <p>24 in general, so that was a very general question, and they</p> <p>25 provided these.</p>	<p>1 Q (By Mr. Williams) And as you sit here today, you do not</p> <p>2 know whether or not the documents that are listed in</p> <p>3 References 40 through 65 are in fact authentic documents</p> <p>4 of Johnson & Johnson or of Imerys, right, one way or the</p> <p>5 other?</p> <p>6 MS. PARFITT: Objection; form.</p> <p>7 THE WITNESS: I don't have memorized</p> <p>8 what these are.</p> <p>9 Q (By Mr. Williams) Pardon me?</p> <p>10 A I don't have memorized what these are, what these numbers</p> <p>11 refer to.</p> <p>12 Q With respect to any of the internal company documents</p> <p>13 that you have reviewed from either Imerys or Johnson &</p> <p>14 Johnson, as you sit here now, you do not know whether any</p> <p>15 of those documents are in fact authentic Johnson &</p> <p>16 Johnson or Imerys documents, correct?</p> <p>17 MS. PARFITT: Objection; form.</p> <p>18 THE WITNESS: When I looked at any of</p> <p>19 these documents that were provided, they had stickers on</p> <p>20 them, I noticed, like-- so exhibit numbers, so I assumed</p> <p>21 this were exhibit numbers for some litigation.</p> <p>22 That's all I know.</p> <p>23 Q (By Mr. Williams) Are you relying on any of those</p> <p>24 internal company documents to form the basis of your</p> <p>25 opinions in this case?</p>

10 (Pages 34 to 37)

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<p>1 MS. PARFITT: Objection; form, vague.</p> <p>2 THE WITNESS: I looked through them.</p> <p>3 I did not read them in enough detail to have them form</p> <p>4 the primary basis of my opinion.</p> <p>5 Q (By Mr. Williams) Do they form something other than a</p> <p>6 primary basis for your opinion?</p> <p>7 A They added to some-- to consideration of what might be</p> <p>8 contained in these products.</p> <p>9 Q Do you have any idea what percentage of the entire</p> <p>10 document production from Johnson & Johnson these 18</p> <p>11 documents comprised?</p> <p>12 A I do not.</p> <p>13 Q When you asked Counsel to provide you with what some of</p> <p>14 the evidence was with respect to the question you were</p> <p>15 being asked to consider, did you ask for both evidence</p> <p>16 that tends to show that, for example, Johnson's Baby</p> <p>17 Powder contains asbestos, and for evidence that it does</p> <p>18 not contain asbestos?</p> <p>19 A I asked about totality of evidence.</p> <p>20 I didn't use the words, "Please show me where it</p> <p>21 contains and where it doesn't."</p> <p>22 One thing I'm interested in is if something contains</p> <p>23 it, that's very concerning to me, so whether it's 50</p> <p>24 samples out of 100 that have asbestos in it, I would be</p> <p>25 concerned, but if it's only five, so even if more</p>	<p>1 question at issue?</p> <p>2 MS. PARFITT: Objection; form.</p> <p>3 THE WITNESS: No, I don't-- well, it</p> <p>4 depends how you define a company, because occasionally if</p> <p>5 you're doing a full review of the scientific literature,</p> <p>6 you may-- for example, if you are doing a meta-analysis,</p> <p>7 they want to request data from other sources that aren't</p> <p>8 yet in the public domain, and if that study happens to be</p> <p>9 run through a company, then that could have happened.</p> <p>10 I can't say it's common.</p> <p>11 Typically we look at published data-- published</p> <p>12 scientific data from scientific opinions.</p> <p>13 Q (By Mr. Williams) When drafting a publication on a</p> <p>14 medical or a scientific question, have you ever sought</p> <p>15 internal company documents related to the subject matter?</p> <p>16 MS. PARFITT: Objection; asked and</p> <p>17 answered.</p> <p>18 THE WITNESS: So I'm curious, is that</p> <p>19 the same question as before? Did you just ask that</p> <p>20 question-- are you asking it again?</p> <p>21 Q (By Mr. Williams) I'll ask it another way.</p> <p>22 A Okay.</p> <p>23 Q Out of the multiple hundreds of publications that your</p> <p>24 resume lists with you as an author, how many cite to</p> <p>25 internal company documents?</p>
Page 39	Page 41
<p>1 negative samples were provided, and there's only five</p> <p>2 that are positive, that's still concerning.</p> <p>3 Q Were you provided any negative samples?</p> <p>4 A I did see evidence that some were negative, yes.</p> <p>5 Q Where did you see that?</p> <p>6 A I saw that in the Longo report, so there was-- each</p> <p>7 report had a different percent that were positive.</p> <p>8 Some were 50 percent positive, some 66 or 70 percent</p> <p>9 positive, so that means the inverse, 30 to 50 percent</p> <p>10 were negative, did not have asbestos.</p> <p>11 Also, from my perusal of the Johnson & Johnson and</p> <p>12 Imerys documents that seem to be exhibits, it looked like</p> <p>13 there were some, but sometimes it was small amounts but</p> <p>14 sometimes it was larger, but that some contamination or</p> <p>15 inclusion of asbestos, but many times not.</p> <p>16 There was also an FDA website that was able to look</p> <p>17 at where they only tested, however, two products, two</p> <p>18 bottles of Johnson & Johnson, and those were both</p> <p>19 negative.</p> <p>20 Q In the normal course of your work outside of litigation,</p> <p>21 do you review internal company documents for any reason?</p> <p>22 A No, not-- I would not have a reason to do that.</p> <p>23 Q When setting out to conduct research on a medical or</p> <p>24 other scientific question, outside of litigation, have</p> <p>25 you ever sought internal company documents related to the</p>	<p>1 MS. PARFITT: Objection; form.</p> <p>2 THE WITNESS: I believe that none do.</p> <p>3 Most of my papers are with data from my own studies.</p> <p>4 Q (By Mr. Williams) Now, you were asked in this matter to</p> <p>5 review the current state of scientific literature</p> <p>6 regarding talcum powder products and to opine on whether</p> <p>7 those products cause ovarian cancer.</p> <p>8 Is that accurate?</p> <p>9 A Yes. I was asked to do a causal analysis and to form an</p> <p>10 opinion on the association between use of talcum powder</p> <p>11 products and risk of ovarian cancer.</p> <p>12 Q Were you given any other questions to answer or opine on?</p> <p>13 A So I'm just looking at your question. I'm sorry.</p> <p>14 I think this summarizes the question I was asked to</p> <p>15 answer.</p> <p>16 Q You were not retained to provide an opinion about whether</p> <p>17 or not talc can cause pleural or peritoneal mesothelioma,</p> <p>18 were you?</p> <p>19 A I was not, no.</p> <p>20 Q And you are not in fact providing an opinion on that</p> <p>21 subject?</p> <p>22 A I am not.</p> <p>23 Q Did you in fact review what you believe to be the current</p> <p>24 state of scientific literature regarding the question of</p> <p>25 whether talc can cause ovarian cancer?</p>

11 (Pages 38 to 41)

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<p style="text-align: right;">Page 42</p> <p>1 A Yes, I believe I did.</p> <p>2 Q Did you consider literature and sources that refuted an</p> <p>3 association or causal association between talc and</p> <p>4 ovarian cancer?</p> <p>5 A Yes, I did.</p> <p>6 I looked at the entirety of literature as I knew</p> <p>7 it-- as I was able to find it.</p> <p>8 Q Did you consider literature and sources that have</p> <p>9 concluded that the totality of the scientific evidence is</p> <p>10 insufficient to find a causal association between talc</p> <p>11 and ovarian cancer?</p> <p>12 MS. PARFITT: Objection; form.</p> <p>13 THE WITNESS: Yes.</p> <p>14 Q (By Mr. Williams) When you wrote your report setting</p> <p>15 forth your opinions in this case, did you identify the</p> <p>16 sources that refuted the propositions that you were</p> <p>17 making?</p> <p>18 A Those papers would have been part of my report, yes.</p> <p>19 Q So is it your testimony that the report that you have in</p> <p>20 front of you, Exhibit No. 2, actually identifies the</p> <p>21 sources that refuted the propositions that you were</p> <p>22 making?</p> <p>23 A Yes.</p> <p>24 If these were papers that included data-- so I use</p> <p>25 data-- I reviewed the data from these studies, and</p>	<p style="text-align: right;">Page 44</p> <p>1 It's in the table, and in the report I did note</p> <p>2 where there was a dose response note-- I did note whether</p> <p>3 there was a dose response seen in the paper.</p> <p>4 I can't-- let me see, I can look through-- I'm not</p> <p>5 sure if you want me to look through for each--</p> <p>6 Q We'll do that a little later.</p> <p>7 A Okay.</p> <p>8 Q Let me ask you now to turn to Page 68 of your report with</p> <p>9 the heading that says, "Conclusion."</p> <p>10 A (Witness complies.)</p> <p>11 Q Do you have that in front of you?</p> <p>12 A Yes.</p> <p>13 Q Does that conclusion accurately summarize your opinion in</p> <p>14 this case on the question of whether or not perineal use</p> <p>15 of talcum powder products can cause ovarian cancer?</p> <p>16 A Yes.</p> <p>17 Q Now, your opinion is stated to a, quote, "medical and</p> <p>18 scientific degree of certainty," closed quote.</p> <p>19 Do you see that?</p> <p>20 A Yes.</p> <p>21 Q What do you mean by the use of the term "degree" in that</p> <p>22 sentence?</p> <p>23 A I would say a high degree.</p> <p>24 I don't put percentages on my opinion. It's not</p> <p>25 typical in my field to do that, but I would say with a</p>
<p style="text-align: right;">Page 43</p> <p>1 regardless of what those studies concluded, I included</p> <p>2 them in the report.</p> <p>3 Q Did you discuss in your report the part or parts within</p> <p>4 those sources that refuted the propositions you were</p> <p>5 making, including the data?</p> <p>6 A I believe that I discussed in general that-- whether</p> <p>7 there is evidence of a causal relationship between talcum</p> <p>8 powder product use and risk of ovarian cancer.</p> <p>9 I did not, for each paper, reiterate what they</p> <p>10 concluded. I looked at their data.</p> <p>11 Q If there were parts of a study, for instance, that did</p> <p>12 not support one of your opinions, did you make a note of</p> <p>13 that in your report?</p> <p>14 MS. PARFITT: Objection; form.</p> <p>15 THE WITNESS: If the studies did not</p> <p>16 show an association between talcum powder product use and</p> <p>17 risk of ovarian cancer, I included those data, yes.</p> <p>18 I included it both in the content of the report as</p> <p>19 well as in the data table that I included at the end of</p> <p>20 the report, and I included those data.</p> <p>21 Q (By Mr. Williams) If those data did not, for instance,</p> <p>22 show a dose response related to exposure to talcum powder</p> <p>23 and the incidence of ovarian cancer, did you note in your</p> <p>24 report where the data did not support dose response?</p> <p>25 A I did note that.</p>	<p style="text-align: right;">Page 45</p> <p>1 high degree of certainty that based on the totality of</p> <p>2 evidence, that use of talcum powder products can cause</p> <p>3 ovarian cancer.</p> <p>4 Q Do you believe that perineal use of talcum powder</p> <p>5 products manufactured today, in 2019, can cause ovarian</p> <p>6 cancer?</p> <p>7 A So talcum powder products, yes.</p> <p>8 There's no evidence that it would have changed.</p> <p>9 The evidence from the epidemiologic studies were</p> <p>10 from people's use decades previously, but then looking at</p> <p>11 contents of talcum powder products over time it looks</p> <p>12 like they continue to have constituents that could be</p> <p>13 carcinogenic, as well as talcum powder by itself has been</p> <p>14 shown to be carcinogenic, and so I believe that if</p> <p>15 somebody was using them today, they could still have the</p> <p>16 same potential for developing ovarian cancer as if they</p> <p>17 used them 50 years ago.</p> <p>18 Q So the answer to my question is that you believe that</p> <p>19 perineal use of talcum powder products manufactured</p> <p>20 today, in 2019, can cause ovarian cancer, correct?</p> <p>21 A Yes-- yes.</p> <p>22 Q Did you reach the opinion, to a degree of medical and</p> <p>23 scientific certainty, that perineal use of talcum powder</p> <p>24 products can cause ovarian cancer before or after you</p> <p>25 were hired by Plaintiffs' counsel?</p>

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<p style="text-align: right;">Page 46</p> <p>1 A After I had conducted a full systematic review of the 2 epidemiology data and mechanistic data, including 3 biologic evidence, and then done a causal analysis, 4 that's when I concluded that these products could 5 increase-- could cause ovarian cancer. 6 Q So the answer is after you were hired by Plaintiffs' 7 counsel; is that correct? 8 MS. PARFITT: Objection; misstates her 9 testimony, asked and answered. 10 Q (By Mr. Williams) I am looking for a temporal answer. 11 So my question is: 12 Did you reach your conclusions before or after you 13 were retained by Plaintiffs' counsel? 14 MS. PARFITT: Objection; form, asked 15 and answered. 16 THE WITNESS: It was after I had done 17 the causal analysis. 18 Q (By Mr. Williams) And that was after you were retained? 19 MS. PARFITT: Objection. 20 THE WITNESS: That was after I did the 21 causal analysis, which was after I began this project 22 with Counsel. 23 Q (By Mr. Williams) Did you consider whether some brands 24 of talcum powder products can cause ovarian cancer but 25 others may not?</p>	<p style="text-align: right;">Page 48</p> <p>1 cause ovarian cancer. 2 Q And that is true whether it's Johnson's Baby Powder or 3 any other talcum powder product? 4 MS. PARFITT: Objection; form. 5 THE WITNESS: Yes. 6 Q (By Mr. Williams) Is it your opinion that genital 7 perineal use of Shower to Shower product specifically can 8 cause ovarian cancer? 9 A To my knowledge it includes both talc, and some percent 10 may include asbestos and other constituents, and so that 11 would be my opinion, yes. 12 Q And same question: 13 Even if Shower to Shower product did not contain 14 asbestos, it is your conclusion that because it contains 15 talc, it can cause ovarian cancer, correct? 16 A Yes. 17 Q And it's your testimony here today that it has been 18 established, to a degree of medical and scientific 19 certainty, that that is the case? 20 A Yes. 21 Q Is it your testimony today that it is accepted in the 22 medical and scientific field that talcum powder causes 23 ovarian cancer? 24 MS. PARFITT: Objection; form. 25 THE WITNESS: I would say that many</p>
<p style="text-align: right;">Page 47</p> <p>1 A The epidemiology data were insufficient to determine 2 whether any particular brand was used by women, except 3 for one study, Cramer, in 2016. 4 It's my understanding that Johnson & Johnson 5 products had the vast proportion of the market share over 6 time, but I did not come to a conclusion that any 7 particular product was causing this. 8 All I know is that use of these products by these 9 women over time increased their risk for ovarian cancer 10 and that it can cause ovarian cancer. 11 Q So it is your opinion that genital perineal use of 12 Johnson's Baby Powder specifically can cause ovarian 13 cancer, correct? 14 A Yes, given that it's been shown to contain asbestos, 15 given that it contains talc, which has been shown to be 16 carcinogenic, then I would say yes, it could be-- it 17 could be a cause of ovarian cancer. 18 Q Let me tease that out a little bit. 19 If the product did not contain asbestos, is it your 20 testimony that-- is it your opinion that genital perineal 21 use of Johnson's Baby Powder can cause ovarian cancer 22 without containing asbestos? 23 A Yes, even without asbestos, my opinion is that talc can 24 increase risk of ovarian cancer, that there are 25 biological mechanisms, and so that these products could</p>	<p style="text-align: right;">Page 49</p> <p>1 scientists, many clinicians do believe that it can cause 2 ovarian cancer. 3 Q (By Mr. Williams) My question is different. 4 My question is whether or not, Dr. McTiernan, it is 5 accepted in the medical and scientific community today 6 that exposure to talcum powder causes ovarian cancer. 7 A And I think I'm having trouble with the word "accepted," 8 so I am not sure specifically what you mean that it was 9 "accepted." 10 Who it is accepted by, does somebody have 11 guidelines, is somebody giving advice to the public-- 12 there are lots of different organizations that you could 13 call "the medical field," so I think that's why I'm 14 having some trouble there. 15 To me it's a question that's not specific enough for 16 me to figure out how to answer it. 17 Q Well, it's one thing if there is a person in the medical 18 or scientific field who holds an opinion and quite 19 another to say that something is generally accepted in 20 the medical and scientific community that a substance 21 causes cancer; isn't that right? 22 MS. PARFITT: Objection; form. 23 THE WITNESS: Yeah, I still have a 24 problem with the word "accepted" because I work in many 25 other areas, and I have seen that there are so many</p>

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<p>1 different opinions by clinicians, by scientists about</p> <p>2 associations, and then it comes to the point of policy</p> <p>3 and coming up with guidelines.</p> <p>4 That's why I am having a little problem answering a</p> <p>5 question of whether it's accepted.</p> <p>6 I think that for me what I can come up with is this</p> <p>7 is my opinion from the research that I've done.</p> <p>8 I can't speak for other medical groups of whatever</p> <p>9 you are talking about.</p> <p>10 I'm not sure which groups you are talking about.</p> <p>11 Q (By Mr. Williams) Wouldn't it be accurate to say,</p> <p>12 Dr. McTiernan, that it is, at best, inconsistent in terms</p> <p>13 of the medical and scientific community as to whether or</p> <p>14 not exposure to talcum powder in the perineal area causes</p> <p>15 ovarian cancer?</p> <p>16 MS. PARFITT: Objection; form.</p> <p>17 THE WITNESS: Oh, I would say that any</p> <p>18 exposure, any medical treatment, any medical prevention</p> <p>19 method is going to be inconsistent, and I do know that</p> <p>20 IARC has classified talc, even talc without asbestos, as</p> <p>21 a possible carcinogen, and they have a pretty high bar</p> <p>22 for whether they're going to consider something a</p> <p>23 carcinogen, and they were talking about ovarian cancer</p> <p>24 specifically.</p> <p>25 Q (By Mr. Williams) We'll talk about that a little bit</p>	<p>1 causes ovarian cancer, isn't it accurate to say that that</p> <p>2 survey is at best inconsistent as to that conclusion?</p> <p>3 MS. PARFITT: Objection; form,</p> <p>4 misstates her testimony-- excuse me, it doesn't misstate</p> <p>5 her testimony. It's been asked and answered, clearly.</p> <p>6 THE WITNESS: I think-- I think from</p> <p>7 what you're asking is I've surveyed the medical community</p> <p>8 and scientific community, which I have not. I have not</p> <p>9 surveyed them.</p> <p>10 My job was to review studies to look at the</p> <p>11 epidemiologic data. That was my primary purpose.</p> <p>12 Then to look at biological mechanisms.</p> <p>13 And then to do a causal analysis.</p> <p>14 I did not contact and survey the medical community</p> <p>15 in this field, which could be vast because we are talking</p> <p>16 about gynecology, prevention, government bodies,</p> <p>17 epidemiology-- I just did not-- I was not asked to do</p> <p>18 that and I did not do that.</p> <p>19 Q (By Mr. Williams) In forming your opinion that perineal</p> <p>20 talc use can cause ovarian cancer, did you calculate how</p> <p>21 much talc is needed to cause ovarian cancer?</p> <p>22 A I looked at that. I was not able to determine because</p> <p>23 there's no-- no study has been able to collect</p> <p>24 information in enough depth to know how much the</p> <p>25 individual woman used, exactly how much in a particular</p>
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<p>1 later, but let me go back to my question.</p> <p>2 My question is whether or not it is at best</p> <p>3 inconsistent, in terms of looking across the available</p> <p>4 medical and scientific information regarding an</p> <p>5 association between talcum powder and causing ovarian</p> <p>6 cancer, to conclude that in fact talcum powder exposure</p> <p>7 in the perineal area causes ovarian cancer; isn't that</p> <p>8 true?</p> <p>9 MS. PARFITT: Objection; form.</p> <p>10 THE WITNESS: So I think I would feel</p> <p>11 a little better if you are talking now about across the</p> <p>12 evidence or across all of this research, all of these</p> <p>13 studies, and there were-- there have been 24 to 25</p> <p>14 case-control cohort studies that have looked at this</p> <p>15 information, and when you look at them in totality,</p> <p>16 either meta-analysis or pooled analysis, you really see</p> <p>17 clear evidence that ovarian cancer risk is higher in</p> <p>18 people who have-- and statistically significantly higher</p> <p>19 in people who have used these products.</p> <p>20 Q (By Mr. Williams) Let me ask you, for purposes of my</p> <p>21 question, to focus on the medical and scientific</p> <p>22 community, okay, not your personal opinion of the data.</p> <p>23 With respect to your survey of the medical and</p> <p>24 scientific community and its analysis of whether or not</p> <p>25 exposure to talcum powder in the perineal area actually</p>	<p>1 day she used, and what was the content of the particular</p> <p>2 bottle that she used or the bottle she used over time,</p> <p>3 and many of the studies did not also even include enough</p> <p>4 information to look at how frequently or how often they</p> <p>5 did, but once they did, then you could see if you had</p> <p>6 people that used it more often for a longer period of</p> <p>7 time, that's when there was even a great increase in</p> <p>8 risk, and that would be a dose response effect.</p> <p>9 Q Is the answer to my question "no," you did not calculate</p> <p>10 how much talc is needed to cause ovarian cancer?</p> <p>11 MS. PARFITT: Objection; form, asked</p> <p>12 and answered.</p> <p>13 Q (By Mr. Williams) I am not asking for the reasons.</p> <p>14 I am just asking for the bottom line.</p> <p>15 The bottom line is that you did not calculate how</p> <p>16 much talc is needed to cause ovarian cancer, correct?</p> <p>17 MS. PARFITT: Objection; form.</p> <p>18 THE WITNESS: It was not possible to</p> <p>19 determine exactly how much talcum powder product was</p> <p>20 used, so therefore it's not possible to determine how</p> <p>21 much of each dose particular-- of a particular product</p> <p>22 increases risk.</p> <p>23 Q (By Mr. Williams) In your mind is there a dose of talc</p> <p>24 that does not cause ovarian cancer when applied</p> <p>25 perineally?</p>

14 (Pages 50 to 53)

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<p style="text-align: right;">Page 54</p> <p>1 A There's no evidence that there's any lower threshold 2 than-- 3 Q I-- I'm sorry. I didn't mean to cut you off. 4 A So the question is there a dose of-- 5 Q Is there a dose of talc that does not cause ovarian 6 cancer when applied perineally? 7 A There's no evidence that there's any lower limit to a 8 dose-- to use of these products that could increase risk. 9 Q It is your testimony here today that a single dose from a 10 single perineal application of talc is enough to cause 11 ovarian cancer based upon your review of the studies? 12 A The studies did not give that level of detail, of whether 13 somebody used one dose in terms of ovarian cancer risk. 14 However, if you think of the biology, if this one 15 dose was introduced perineal, then could move up through 16 the vagina, through the cervix and the uterus, and get to 17 just as far as the fallopian tubes, if it sits in there 18 and causes an inflammatory reaction, theoretically one 19 dose could be enough. 20 Typically in epidemiologic studies we look for dose 21 response, so if somebody is using something longer, more 22 time, more frequently, that increases the chance that 23 some of that content could get up into her perineal-- 24 sorry, her peritoneal, fallopian tubes, ovaries, but 25 there's no reason that one dose couldn't do that.</p>	<p style="text-align: right;">Page 56</p> <p>1 MS. PARFITT: Objection; asked and 2 answered. 3 She has responded. 4 THE WITNESS: I am saying I couldn't 5 find data from the studies about one dose, the effect of 6 one dose on ovarian cancer, but I am saying that one dose 7 could cause inflammation. 8 Q (By Mr. Williams) When you said "theoretically one dose 9 could be enough," you were speculating, correct? 10 MS. PARFITT: Objection; asked and 11 answered, and she has given you the answer, Mr. Williams. 12 THE WITNESS: I am saying I don't have 13 the data to say exactly. 14 Q (By Mr. Williams) You don't have the data to say one way 15 or the other? 16 MS. PARFITT: Objection; misstates her 17 testimony. 18 THE WITNESS: I don't have the data on 19 ovarian cancer and one dose. 20 MS. PARFITT: Mr. Williams, without 21 breaking any train of thought, we have gone about an hour 22 and 15 minutes. Maybe in an appropriate place, we could 23 take a minute, but I don't want to break your stride. 24 MR. WILLIAMS: In a minute. Thank 25 you.</p>
<p style="text-align: right;">Page 55</p> <p>1 We do know from the biology that one dose of talc 2 injected either into the pleura or into the lungs can 3 cause an inflammatory response. 4 Q When you say "theoretically one dose could be enough," 5 you are speculating; are you not? 6 MS. PARFITT: Objection; misstates her 7 testimony, form. 8 THE WITNESS: I am saying that we know 9 from other evidence, the biology, that if one dose is 10 injected into the pleura, and I'm talking humans, or 11 inhaled into the lungs, one dose can cause an 12 inflammatory response, so that's why I believe one dose 13 could cause a response in the peritoneal area-- sorry, in 14 the fallopian tube or ovarian area. 15 Q (By Mr. Williams) You used the phrase "theoretically one 16 dose could be enough," did you not, in your answer a few 17 moments ago? 18 A I said that because it would be unethical to introduce 19 one dose of this substance into the fallopian tubes or 20 ovary area, so you couldn't test that in a human 21 directly. 22 Q My question is different, ma'am. 23 My question is that you are the person in the room 24 who used the phrase "theoretically one dose could be 25 enough" just a few moments ago, correct?</p>	<p style="text-align: right;">Page 57</p> <p>1 Q (By Mr. Williams) When you said a few moments ago that 2 you believe that even one dose could cause inflammation, 3 based upon your review of the science, have you reviewed 4 scientific literature, any study that says talcum powder 5 causes inflammation, which inflammation causes ovarian 6 cancer? 7 A The evidence that I was able to look at, because you can 8 not do-- ethically you cannot do a clinical trial where 9 you expose women to talcum powder products in one group 10 and a placebo in another and then follow them forward for 11 30 or 40 years to see if you develop ovarian cancer-- 12 because that trial cannot be done, we have to look at 13 different lines of evidence, so we look at the 14 epidemiology, we look at whether materials can be 15 introduced into the peritoneal area and make their way up 16 through the vaginal tract and get to the fallopian tubes 17 or ovaries, and then we know that inflammation does 18 increase risk for ovarian cancer. 19 There have been many studies that show that 20 individuals with high levels of inflammatory markers in 21 their blood, for example, have increased risk for ovarian 22 cancer, and people with inflammatory conditions, again, 23 endometriosis, are at an increased risk for ovarian 24 cancer. 25 Q Does all inflammation cause cancer, ma'am?</p>

15 (Pages 54 to 57)

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<p style="text-align: right;">Page 58</p> <p>1 A It's not clear that all does, but it certainly increases 2 risk. 3 Q So the answer is "no," not all inflammation causes 4 cancer? 5 MS. PARFITT: Objection; misstates her 6 testimony. 7 THE WITNESS: I am saying that the 8 inflammation-- increased inflammation is associated with 9 increased risk for cancer. 10 Q (By Mr. Williams) What types of cancer? 11 A For example, some inflammatory conditions like Crohn's 12 disease increases risk for colon cancer. 13 Individuals with rheumatoid arthritis have increased 14 risk for lymphoma. 15 Those inflammatory markers that I mentioned, like 16 C-reactive protein and to interleukin 6 or 8, if those 17 are increased, all those are can increase risk for breast 18 cancer, ovarian cancer, colon cancer, and other cancers. 19 Q Now, you have a medical degree, correct? 20 A Mm-hm. 21 Q Is that a "yes"? 22 A Yes. 23 Q And you held a license to practice medicine in the state 24 of Washington from July of 1991 to February 18th of 2018; 25 is that right?</p>	<p style="text-align: right;">Page 60</p> <p>1 there. 2 The work I do for the World Cancer Research Fund 3 looks at association of diet and physical activity and 4 obesity, and risk of cancer and ovarian cancer is one of 5 those. 6 Q I didn't mean to include the work you have done on the 7 World Cancer Research Fund. I meant separately published 8 articles of the sort that are referenced on your CV. 9 Did you understand that to be my question? 10 A Yes. 11 So the first one is in press for 2019, for March of 12 2019, and ovarian was one of those cancers. 13 Q And where is that to be published? 14 A Medicine & Science in Sports & Exercise. 15 Q Have you ever given any lectures regarding talcum powder 16 products and ovarian cancer? 17 A No, I have not. 18 Q Have you ever given any presentations regarding talcum 19 powder products and ovarian cancer? 20 A No, I haven't. 21 Q Have you ever posted on social media at all regarding 22 talcum powder products and ovarian cancer? 23 A I don't believe so. 24 Q Have you ever written any textbook chapters regarding 25 talcum powder products and ovarian cancer?</p>
<p style="text-align: right;">Page 59</p> <p>1 A I apologize, it's still active. I still have a license. 2 Q And you held what's known as a DEA license that allows 3 one to prescribe medicines? 4 A Yes. 5 Q Is that still active? 6 A That's still active, yes. 7 Q Is it accurate to say that you have never been a 8 gynecological oncologist? 9 A That's accurate. 10 Q Now, you have written two articles about how diet and 11 exercise affect women after they have been diagnosed with 12 gynecologic cancer, correct? 13 A At least two, yeah. 14 Q None of the articles that you've written on that topic 15 studied what causes or may cause gynecological cancers; 16 is that true? 17 A That's correct. 18 Q Can we agree that you have never written any 19 peer-reviewed, published article or study on the causes 20 of ovarian cancer? 21 A If we're talking about an overall general article, that's 22 true. 23 However, we have a paper in press that is looking at 24 the association of physical activity with various 25 cancers, and ovarian cancer was one that was included</p>	<p style="text-align: right;">Page 61</p> <p>1 A No, I haven't. 2 Q You are not and were not ever an oncologist of any kind? 3 A No. 4 Q You are not a pathologist, correct? 5 A No. 6 Q You are not a cancer biologist, right? 7 A No. 8 Q You are not a toxicologist? 9 A No. 10 Q You are not an industrial hygienist? 11 A No. 12 Q Prior to being hired by the Plaintiffs' lawyers in talc 13 litigation, you had not personally conducted research on 14 talcum powder product use and risk for ovarian cancer, 15 true? 16 MS. PARFITT: Objection; misstates her 17 testimony, form. 18 THE WITNESS: Let me look at the-- 19 prior to being hired-- it depends on what you consider 20 research because I had read some articles, but I had not 21 produced a report in that area. 22 Q (By Mr. Williams) Let me put it this way: 23 You have published several manuscripts on 24 gynecologic cancers, including the prevention of ovarian 25 cancer in women at high genetic risk, correct?</p>

16 (Pages 58 to 61)

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<p>1 A Yes.</p> <p>2 Q And you have published manuscripts regarding the effects</p> <p>3 of weight and exercise on the risk for ovarian cancer,</p> <p>4 correct?</p> <p>5 A Yes.</p> <p>6 Q But you have not personally conducted research on talcum</p> <p>7 powder use and risk for ovarian cancer, correct?</p> <p>8 MS. PARFITT: Objection.</p> <p>9 THE WITNESS: The report that I've</p> <p>10 just prepared I would say is research because it was a</p> <p>11 systematic review.</p> <p>12 Q (By Mr. Williams) Let me have you look at Exhibit No. 2,</p> <p>13 your report, and then we'll take a break in a minute.</p> <p>14 A (Witness complies.)</p> <p>15 Q Could you turn to Page 6, please?</p> <p>16 The first full paragraph on Page 6 begins by saying,</p> <p>17 "Although I have not personally conducted research on</p> <p>18 talcum powder product use and risk for ovarian cancer, I</p> <p>19 have published several manuscripts," and it goes on.</p> <p>20 Do you see that?</p> <p>21 A Yes.</p> <p>22 Q Is the first clause in that sentence true or not true?</p> <p>23 A Yes, that's true.</p> <p>24 Q Let's just mark, before we take a break, these other</p> <p>25 items we said we were going to mark.</p>	<p>1 Q (By Mr. Williams) Dr. McTiernan, before you were ever</p> <p>2 retained as a paid consultant for this litigation in the</p> <p>3 fall of 2016, you had written literally hundreds of</p> <p>4 articles for peer-reviewed journals.</p> <p>5 Is that true?</p> <p>6 A Yes.</p> <p>7 Q You have worked on comprehensive written reports for the</p> <p>8 U.S. government in your career?</p> <p>9 A Yes.</p> <p>10 Q Can you just describe very briefly, if you would, the</p> <p>11 types?</p> <p>12 A The U.S. government, I did two reports on physical</p> <p>13 activity and cancer risk and survival, 2008 and 2018, so</p> <p>14 this was the-- it's called a physical activity guidelines</p> <p>15 advisory committee, and for that we relied on</p> <p>16 meta-analyses. We did not do our own research.</p> <p>17 I've also over the years done grant reviews for the</p> <p>18 government. I have reviewed their intramural program, so</p> <p>19 that means their science, have reviewed their science,</p> <p>20 and I have prepared reports years ago for National Cancer</p> <p>21 Institute for-- I've done grant reviews for other</p> <p>22 country's governments.</p> <p>23 That's my governmental service.</p> <p>24 I was on-- sorry, the United States government</p> <p>25 still-- grant reviews for the Department of Defense and</p>
Page 63	Page 65
<p>1 First is Exhibit No. 3, we would like to mark it,</p> <p>2 "Additional materials to Dr. Anne McTiernan."</p> <p>3 (Exhibit No. 3 marked</p> <p>4 for identification.)</p> <p>5</p> <p>6 Q (By Mr. Williams) Now, I think you told us that the</p> <p>7 additional materials that you brought here today support</p> <p>8 your opinions; is that correct?</p> <p>9 A Yes.</p> <p>10 Q Other than believing that those materials you brought</p> <p>11 today support your opinions with respect to the</p> <p>12 association between perineal talcum powder use and</p> <p>13 ovarian cancer, have your opinions changed at all since</p> <p>14 you first prepared your report that we've marked as</p> <p>15 Exhibit No. 2?</p> <p>16 A No, they have not.</p> <p>17 MR. WILLIAMS: Thanks. Let's take a</p> <p>18 quick break, about ten minutes.</p> <p>19 VIDEOGRAPHER: Going off the record,</p> <p>20 the time is 10:28 a.m.</p> <p>21 (Recess 10:28 to 10:40 a.m.)</p> <p>22</p> <p>23 VIDEOGRAPHER: The time is 10:40 a.m.</p> <p>24 We are back on the record. This is the start of Media</p> <p>25 Unit 2.</p>	<p>1 the National Institute of Health.</p> <p>2 Q Let me ask you to look in your report, Exhibit No. 2, at</p> <p>3 Page No. 7.</p> <p>4 In the section of your report entitled, "Overall</p> <p>5 approach," you write, in the second sentence, "I drew</p> <p>6 upon my years of experience with synthesizing and</p> <p>7 interpreting large numbers of epidemiologic studies for</p> <p>8 comprehensive reports, including work for the U.S.</p> <p>9 government," and we have gone through that, right?</p> <p>10 A Mm-hm.</p> <p>11 Q Is that a "yes"?</p> <p>12 A Yes. Sorry.</p> <p>13 Q You go on to say, "the World Health Organization,</p> <p>14 International Agency for Research on Cancer"-- IARC,</p> <p>15 correct?</p> <p>16 A Yes.</p> <p>17 Q --"and the World Cancer Research Fund," correct?</p> <p>18 A Yes.</p> <p>19 Q And you have drawn upon your experience with all of those</p> <p>20 organizations in setting forth your conclusions here?</p> <p>21 A Yes.</p> <p>22 Q And that's what you write in your report?</p> <p>23 A Yes.</p> <p>24 Q And you write that your opinions are based on the</p> <p>25 published epidemiologic evidence, including original</p>

17 (Pages 62 to 65)

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<p>1 case-control and cohort studies, systematic reviews, 2 meta-analyses, and pooled analyses on the topic of talcum 3 powder products exposure and a risk of ovarian cancer, 4 correct? 5 A Yes, that's what I wrote. 6 Q Okay. For the World Cancer Research Fund, you are a 7 member of the advisory panel of experts that guides 8 interpretation of meta-analyses and systematic reviews of 9 nutrition, physical activity, obesity, and risk for many 10 cancers, correct? 11 A Yes, that's correct. 12 Q On Page 5, if you flip one page earlier, you reference, 13 in the section of your report citing your credentials, 14 the work that you have done for the World Cancer Research 15 Fund, right? 16 A Yes. 17 Q In the middle of the page on Page 5 of Exhibit No. 2 you 18 say, "For the World Cancer Research Fund, I am a member 19 of the advisory panel of experts that guides 20 interpretation of meta-analyses and systematic reviews of 21 nutrition, physical activity, obesity, and risk for many 22 cancers, including ovarian cancer," right? 23 A Yes. 24 Q And you have a link there to an ovarian cancer 2014 25 report that you did, right?</p>	<p>1 cancers. 2 I can't say who wrote them because I never quite 3 know who exactly did what-- what one person did the main 4 report drafting. 5 Q As a panel member, you read the reports though, right? 6 A Yes. 7 Q As a panel member you make recommendations based on the 8 reports, don't you? 9 A Say it again-- 10 Q As a panel member-- 11 A You make recommendations-- that means to them or to-- 12 Q To the public. 13 Let me rephrase the question. 14 As a panel member for the World Cancer Research 15 Fund, the WCRF, you read the reports that are prepared by 16 that organization and make recommendations to the public 17 based upon those reports, right? 18 A I do read the reports. I give input because I'm part of 19 a panel. It doesn't mean I can drive exactly what gets 20 sent there. 21 When the public recommendations come out, we are 22 given a set of guidelines that if there are 23 recommendations that are developed, they will be 24 standardized, and we are asked to follow those standards. 25 I cannot develop my own standards for what</p>
Page 67	Page 69
<p>1 A Yes. 2 Q And that-- 3 A Maybe I could correct that. 4 I'm on the advisory panel. I don't prepare those 5 reports. 6 I help interpret them, but it's the World Cancer 7 Research Fund scientists-- sorry, Imperial College does 8 the meta-analyses and the systematic reviews, and then 9 the World Cancer Research Fund has scientists that write 10 the reports. 11 As an advisory committee member, I give opinions 12 on-- with the rest of the committee on-- and we summarize 13 what we think we are seeing in those-- in the data. 14 Q So just to make sure that I understand the process, the-- 15 you mentioned that there are staff members, I suppose, 16 from Imperial College who actually write the reports? 17 A The staff members-- the scientists from Imperial College 18 do the meta-analyses. They collect the data from all 19 available studies, and they prepare data tables, and 20 there are scientists at World Cancer Research Fund-- so 21 it's a funding organization and a scientific 22 organization, so their scientists write the reports. 23 For some of these cancers they also contract to 24 the-- to IARC, to scientists there who will write some of 25 the background epidemiology and the biology of particular</p>	<p>1 recommendations or what statements are made to the public 2 from that. 3 (Exhibit No. 4 marked 4 for identification.) 5 6 Q (By Mr. Williams) Let me have you take a look at what 7 we've marked as Exhibit No. 4, which is a copy of this 8 report that you provided a link to in your report at Page 9 5. 10 Page 5 of your report in this case, Exhibit No. 2-- 11 Dr. McTiernan, can I have your attention? 12 A Yes. 13 Q In the report that you wrote for this case at Page No. 5, 14 you provided a link. 15 Do you see that? 16 A Yes. 17 Q That link is to a report that you are holding in your 18 hand, which is a 2014 ovarian cancer report, "Food, 19 nutrition, physical activity, and prevention of ovarian 20 cancer" that was prepared by the World Cancer Research 21 Fund, right? 22 A Correct. 23 Q In the bottom right-hand corner of the page do you see 24 there's a logo for something called the Continuous Update 25 Project?</p>

18 (Pages 66 to 69)

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<p style="text-align: right;">Page 70</p> <p>1 A Yes.</p> <p>2 Q That is the "CUP" for short?</p> <p>3 A Yes.</p> <p>4 Q You helped to oversee the CUP as part of its expert</p> <p>5 panel, true?</p> <p>6 A I'm on an advisory committee for this project.</p> <p>7 Q Take a look at Page 20 of Exhibit No. 4-- actually, Page</p> <p>8 19, the acknowledgments section.</p> <p>9 Do you have that in front of you?</p> <p>10 A Yes.</p> <p>11 Q And that lists the panel members, correct?</p> <p>12 A Correct.</p> <p>13 Q And amongst the ten panelists, you are listed, right?</p> <p>14 A Yes.</p> <p>15 Q And the chair is Alan Jackson from the University of</p> <p>16 Southampton in Southampton, UK, right?</p> <p>17 A Correct.</p> <p>18 Q You are still on the CUP panel today, are you?</p> <p>19 A It's not clear.</p> <p>20 I am advising on survivorship issues.</p> <p>21 It's not clear if this panel will continue.</p> <p>22 My term on it finished very recently, and we are</p> <p>23 renegotiating who is going to be on it and what it's</p> <p>24 going to look like for the future.</p> <p>25 Q In 2018--</p>	<p style="text-align: right;">Page 72</p> <p>1 convincing cause of ovarian cancer; is that true?</p> <p>2 A Can you point to where you see this?</p> <p>3 Q Page 5.</p> <p>4 I will direct your attention to the bottom of the</p> <p>5 page.</p> <p>6 It says, "The CUP panel judges as follows," right?</p> <p>7 A Yes.</p> <p>8 Q And it says the CUP panel-- that's the panel that you sit</p> <p>9 on, right?</p> <p>10 A Yes.</p> <p>11 Q That isn't the people who write it and that isn't the</p> <p>12 people who review the science. That's you, right?</p> <p>13 A Correct.</p> <p>14 Q And it says that "The evidence that developmental factors</p> <p>15 leading to greater linear growth (marked by adult</p> <p>16 attained height) are a cause of ovarian cancer is</p> <p>17 convincing."</p> <p>18 That's what the panel wrote, correct, or</p> <p>19 recommended?</p> <p>20 A That's correct.</p> <p>21 Q Strike that.</p> <p>22 That's what the panel "judged," is the word that's</p> <p>23 used, correct?</p> <p>24 A Correct.</p> <p>25 Q Is that another way of saying that factors that make some</p>
<p style="text-align: right;">Page 71</p> <p>1 A I was a part of it, yes--</p> <p>2 Q You need to let me finish.</p> <p>3 In 2018 you were a part of the panel, correct?</p> <p>4 A Correct.</p> <p>5 Q Let's take a look at Page 1 of Exhibit No. 4, which</p> <p>6 describes the mission with reference to the World Cancer</p> <p>7 Research Fund Global Network.</p> <p>8 It says, "Our mission: Today the World Cancer</p> <p>9 Research Fund Global Network continues," and it mentions</p> <p>10 funding, interpreting the accumulated scientific</p> <p>11 literature in the field, and educating people about</p> <p>12 choices, correct?</p> <p>13 A Correct.</p> <p>14 Q And then at the bottom of Page 1 it references the World</p> <p>15 Cancer Research Fund Global Network, and in that</p> <p>16 paragraph it references, among others, the American</p> <p>17 Institute for Cancer Research, which is the AICR, right?</p> <p>18 A Yes.</p> <p>19 Q And on the first-- the cover page of this document, you</p> <p>20 see the AICR is referenced up at the top with the World</p> <p>21 Cancer Research Fund, right?</p> <p>22 A Yes.</p> <p>23 Q As a member of the panel, you concluded that</p> <p>24 developmental factors leading to greater linear growth,</p> <p>25 which is marked by adult-attained height, are a</p>	<p style="text-align: right;">Page 73</p> <p>1 people taller than others cause ovarian cancer?</p> <p>2 MS. PARFITT: Objection; form.</p> <p>3 THE WITNESS: This panel did not do a</p> <p>4 full causal analysis.</p> <p>5 It does-- its purpose is quite different from the</p> <p>6 purpose of the report I prepared on talcum powder</p> <p>7 products and ovarian cancer risk.</p> <p>8 The purpose is not to establish causality but rather</p> <p>9 to come up with guidelines for those variables that can</p> <p>10 be interpreted into-- can be interpreted into guidelines.</p> <p>11 There is a set of information on how these different</p> <p>12 categories are formed, for convincing, probable</p> <p>13 associations, and then later what can be done for that,</p> <p>14 what kind of recommendations can be made to the public.</p> <p>15 MR. WILLIAMS: Move to strike that as</p> <p>16 nonresponsive, Doctor, if we were in court, and I will do</p> <p>17 that now for the record.</p> <p>18 Q (By Mr. Williams) I would like to ask you to answer my</p> <p>19 question.</p> <p>20 My question is whether that first paragraph there,</p> <p>21 under the "CUP panel judges as follows," is that</p> <p>22 paragraph another way of saying that factors that make</p> <p>23 some people taller than others cause ovarian cancer?</p> <p>24 MS. PARFITT: Objection; form, asked</p> <p>25 and answered.</p>

19 (Pages 70 to 73)

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<p style="text-align: right;">Page 74</p> <p>1 THE WITNESS: So I still want to</p> <p>2 under-- state that we didn't do a full causal analysis,</p> <p>3 but there is a statement here that says these are</p> <p>4 causes-- the panel considers the strength strong enough</p> <p>5 that adult height and body fatness are causes of ovarian</p> <p>6 cancer.</p> <p>7 Q (By Mr. Williams) Does "greater linear growth" mean</p> <p>8 height?</p> <p>9 A It may not mean-- so this particular variable is never</p> <p>10 measured.</p> <p>11 You don't have the data in a population to look at</p> <p>12 linear growth over time, and so they were looking at just</p> <p>13 by adult height.</p> <p>14 Because adult height can be-- have so many variables</p> <p>15 associated with it -- genetic, nutrition -- they didn't</p> <p>16 want to assume that it's only genetic association that is</p> <p>17 driving the risk of cancer, so that's why they're talking</p> <p>18 about growth, but it's a difficult variable because you</p> <p>19 can't tell which cause the eventual adult height and</p> <p>20 which of those parts are associated with ovarian cancer</p> <p>21 or any cancer.</p> <p>22 Q You keep saying "they"-- saying "they" in your answers.</p> <p>23 This is you. This is the CUP panel that made that</p> <p>24 judgment that is set forth in Paragraph No. 1, true or</p> <p>25 not true?</p>	<p style="text-align: right;">Page 76</p> <p>1 No. 4, was not exclusively related to diet and exercise,</p> <p>2 was it?</p> <p>3 A I believe it was.</p> <p>4 Q Let me see if I can help you there.</p> <p>5 You consider causes of ovarian cancer other than</p> <p>6 those relating to diet and exercise, true?</p> <p>7 MS. PARFITT: Objection; form.</p> <p>8 THE WITNESS: From my knowledge the</p> <p>9 meta-analysis work was focused on nutrition variables,</p> <p>10 physical activity variables, and obesity-related</p> <p>11 variables, all because they are related to nutrition, as</p> <p>12 well as lactation because that's also a nutrition-related</p> <p>13 variable.</p> <p>14 Q (By Mr. Williams) Your panel wrote about causes of</p> <p>15 ovarian cancer other than those relating to diet and</p> <p>16 exercise, true?</p> <p>17 MS. PARFITT: Objection; form.</p> <p>18 THE WITNESS: The panel did not-- I</p> <p>19 will have to look and see what they said about other</p> <p>20 causes, but the panel was focused on, in terms of the</p> <p>21 meta-analysis, the new data that they are presenting, is</p> <p>22 all related to nutrition, physical activity, and diet.</p> <p>23 Q (By Mr. Williams) Whether it's new data-- strike that.</p> <p>24 First of all, Doctor, you said "they" again.</p> <p>25 You mean you, you mean "our panel," correct?</p>
<p style="text-align: right;">Page 75</p> <p>1 A Correct, it was the panel.</p> <p>2 MS. PARFITT: Objection.</p> <p>3 Q (By Mr. Williams) The second paragraph says, "Greater</p> <p>4 body fatness, which the panel interprets to be marked by</p> <p>5 the body mass index, is probably a cause of ovarian</p> <p>6 cancer."</p> <p>7 Do you see that?</p> <p>8 A Yes.</p> <p>9 Q That was a judgment made by the panel upon which you sit,</p> <p>10 correct?</p> <p>11 A Correct.</p> <p>12 Q The third paragraph says, "The evidence suggesting that</p> <p>13 lactation protects against ovarian cancer is limited."</p> <p>14 That too was a panel judgment made by the panel upon</p> <p>15 which you sit, right?</p> <p>16 A Correct.</p> <p>17 Q The panel that you were on, at least as of 2018, was</p> <p>18 primarily looking at causes of ovarian cancer related to</p> <p>19 diet and exercise; is that accurate?</p> <p>20 A The panel only looks at those related variables.</p> <p>21 Lactation is included because it has some</p> <p>22 nutritional components, but all of the variables that</p> <p>23 this organization looks at and-- that's their mission.</p> <p>24 The nutrition-related variables is what they look at.</p> <p>25 Q But the panel report that is in front of you, Exhibit</p>	<p style="text-align: right;">Page 77</p> <p>1 A When I say "they," the meta-analysis, I did not do the</p> <p>2 meta-analysis.</p> <p>3 the meta-analysis was done by Imperial College.</p> <p>4 The meta-analysis was contracted by World Cancer</p> <p>5 Research Fund to Imperial College to do those</p> <p>6 meta-analysis.</p> <p>7 What the panel did is-- we're a group of scientists.</p> <p>8 We review those data once they're done.</p> <p>9 Q You review the data once it's done?</p> <p>10 A Once it's done.</p> <p>11 Q And you make recommendations as a panel member, correct?</p> <p>12 A We make judgments.</p> <p>13 The recommendations are a combination of us and</p> <p>14 WCRF.</p> <p>15 Q One of the judgments that is-- strike that.</p> <p>16 On Page 7 of the document, Exhibit No. 4, there is a</p> <p>17 listing entitled, "Other established causes."</p> <p>18 Do you see that?</p> <p>19 A Yes.</p> <p>20 Q And those are established causes of ovarian cancer,</p> <p>21 correct?</p> <p>22 A Correct.</p> <p>23 Q That paragraph--</p> <p>24 A Sorry, say that again.</p> <p>25 Q The other established causes that are being referred to</p>

20 (Pages 74 to 77)

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<p style="text-align: right;">Page 78</p> <p>1 here are established causes of ovarian cancer, correct?</p> <p>2 MS. PARFITT: Objection; form.</p> <p>3 Q (By Mr. Williams) Do you understand my question?</p> <p>4 A I do.</p> <p>5 What I'm trying to say-- what I want to say here is</p> <p>6 there was no systematic review done here.</p> <p>7 This was information that was largely taken from the</p> <p>8 second expert report and repeated here, so this was data</p> <p>9 from 2007-- information from 2007, and there was no--</p> <p>10 except for lactation, among all these variables there was</p> <p>11 no new review done by the panel.</p> <p>12 This was the knowledge at the time of the second</p> <p>13 annual report, 2007, of variables that are-- that the</p> <p>14 2007 expert panel thought were related to ovarian cancer.</p> <p>15 Q Hold on, Doctor.</p> <p>16 In 2014, which is the date of this document, you</p> <p>17 were sitting on the World Cancer Research Fund's panel,</p> <p>18 correct?</p> <p>19 A Correct.</p> <p>20 Q The panel reviews the results of the epidemiological</p> <p>21 analysis that is done by others, correct?</p> <p>22 A Reviews the data, the meta-analysis from the nutrition</p> <p>23 variables, yes.</p> <p>24 Q And then it sets forth judgments and it writes the text</p> <p>25 that appears in this document, correct?</p>	<p style="text-align: right;">Page 80</p> <p>1 probable cause of ovarian cancer, true?</p> <p>2 A If you're talking about this paragraph, I don't see it</p> <p>3 there.</p> <p>4 Q And this paragraph does not describe talc as a risk</p> <p>5 factor for ovarian cancer, such as hormone replacement</p> <p>6 therapy, correct?</p> <p>7 A Talcum powder products are not mentioned there, correct.</p> <p>8 Q This 2004 CUP report-- strike that.</p> <p>9 Did this 2014 CUP report come out before or after</p> <p>10 Plaintiffs' counsel hired you as an expert in this case?</p> <p>11 A This came out before I was hired.</p> <p>12 This was a 2014 report.</p> <p>13 We may have downloaded this recently.</p> <p>14 The way these reports work is the work for the</p> <p>15 meta-analysis is done, and then the panel reviews the</p> <p>16 data, and then a report is drafted and published online</p> <p>17 at that time, so if it says, "2014," then it would have</p> <p>18 been online in 2014, would have been public then.</p> <p>19 Q And there have been reports that have been prepared by</p> <p>20 the World Cancer Research Fund and the American Institute</p> <p>21 for Cancer Research since this 2014 report, right?</p> <p>22 MS. PARFITT: Objection to the form.</p> <p>23 THE WITNESS: Different cancers would</p> <p>24 have been since then.</p> <p>25 I don't have memorized exactly when the different</p>
<p style="text-align: right;">Page 79</p> <p>1 A The panel did not write this text.</p> <p>2 The panel-- the World Cancer Research Fund wrote</p> <p>3 this text.</p> <p>4 Q Are you disavowing Page 7, third paragraph, "Other</p> <p>5 established causes," that's set forth other established</p> <p>6 causes for ovarian cancer?</p> <p>7 MS. PARFITT: Objection; form,</p> <p>8 misstates her testimony.</p> <p>9 THE WITNESS: The question was am I</p> <p>10 disavowing-- I am not disavowing.</p> <p>11 I am saying it was not written by our panel.</p> <p>12 We reviewed it. We had opportunity to have input,</p> <p>13 but we were not the final authors of this section.</p> <p>14 Q (By Mr. Williams) When you read the section, did you</p> <p>15 say, "Wait a minute, you haven't included anything in</p> <p>16 here about talc causing ovarian cancer"?</p> <p>17 Did you tell anybody that?</p> <p>18 A I don't recall doing that.</p> <p>19 At the time I had not done a full analysis of</p> <p>20 ovarian cancer risk factors.</p> <p>21 Q When you say that you don't recall doing it, are you</p> <p>22 saying it might have happened, it might not have</p> <p>23 happened, or are you saying that it did not happen?</p> <p>24 A It did not happen.</p> <p>25 Q This document does not include talc as a cause or</p>	<p style="text-align: right;">Page 81</p> <p>1 years came out.</p> <p>2 In-- last spring, and I think it was 2018, but it</p> <p>3 could have been 2017, there was a final report of WCRF</p> <p>4 that included all of these reports, but this was not</p> <p>5 changed at that time.</p> <p>6 The final report that came out was more of a global</p> <p>7 summary and global nutrition recommendations, but these</p> <p>8 all-- that's why it's called the Continuous Update</p> <p>9 Project, because these things are updated at various</p> <p>10 points and then they become part of that final report,</p> <p>11 2017, 2018.</p> <p>12 This is why I was-- I said that the panel may be</p> <p>13 reconstituted, because we finished one set of cancers,</p> <p>14 one set of reports.</p> <p>15 Q (By Mr. Williams) The whole idea of the CUP reports is</p> <p>16 that they get updated continuously, right?</p> <p>17 MS. PARFITT: Objection; form.</p> <p>18 THE WITNESS: The ovarian cancer was</p> <p>19 not updated after 2014.</p> <p>20 Is that your question?</p> <p>21 Q (By Mr. Williams) Are you sure about that?</p> <p>22 A From my knowledge it was not updated.</p> <p>23 Q Take a look at Page 2 of Exhibit No. 4 that you have.</p> <p>24 At the top of Page 2 it says, "Please cite the</p> <p>25 report as follows," and it gives instructions about how</p>

21 (Pages 78 to 81)

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<p style="text-align: right;">Page 82</p> <p>1 the report should be cited, correct?</p> <p>2 A Yes.</p> <p>3 Q It's accurate to say that the expectation of the</p> <p>4 publication of this report is that it may be cited by</p> <p>5 others, right?</p> <p>6 A Yes.</p> <p>7 Q That's why you have this at the top of Page No. 2,</p> <p>8 correct?</p> <p>9 A Yes.</p> <p>10 Q Let me show you another document, which we'll mark as</p> <p>11 Exhibit No. 5.</p> <p>12 (Exhibit No. 5 marked</p> <p>13 for identification.)</p> <p>14</p> <p>15 Q (By Mr. Williams) Exhibit No. 5, for the record, is a</p> <p>16 multi-page document that says, "Diet, nutrition, physical</p> <p>17 activity and ovarian cancer - revised 2018" on the cover</p> <p>18 page.</p> <p>19 Do you see that?</p> <p>20 A Yes.</p> <p>21 Q The CUP expert panel that you sat on through 2018 issued</p> <p>22 this collection of reports entitled, "Diet, nutrition,</p> <p>23 physical activity and cancer, a global perspective,"</p> <p>24 right?</p> <p>25 A Yes.</p>	<p style="text-align: right;">Page 84</p> <p>1 A Correct.</p> <p>2 Q The CUP expert panel that you sat on through last year is</p> <p>3 in fact the body that issues these reports, like Exhibit</p> <p>4 No. 5, correct?</p> <p>5 A Correct.</p> <p>6 Q Now let me have you look at Exhibit No. 5, which is the</p> <p>7 2018 CUP report.</p> <p>8 I will just quickly refer you to Page 4.</p> <p>9 On Page 4 there's a heading that says, "Our</p> <p>10 Continuous Update Project, CUP"-- do you see that?</p> <p>11 A Yes.</p> <p>12 MS. PARFITT: Give her just one</p> <p>13 moment.</p> <p>14 Q (By Mr. Williams) And then the second paragraph says,</p> <p>15 "An independent panel of experts carries out ongoing</p> <p>16 evaluations of this evidence, and their findings form the</p> <p>17 basis of the WCRF network's cancer prevention</p> <p>18 recommendations."</p> <p>19 Do you see that?</p> <p>20 A Yes.</p> <p>21 Q That's referring to your panel, correct?</p> <p>22 A Yes.</p> <p>23 Q And if you look at the back of this document that's on</p> <p>24 Page 21, in the acknowledgments section, it lists the</p> <p>25 panel members.</p>
<p style="text-align: right;">Page 83</p> <p>1 Q This is the most recent version of the Continuous Update</p> <p>2 Project report that we were just looking at, right?</p> <p>3 A Yes.</p> <p>4 Q Let me show you another document, which is-- we'll mark</p> <p>5 as Exhibit No. 6.</p> <p>6 (Exhibit No. 6 marked</p> <p>7 for identification.)</p> <p>8</p> <p>9 Q (By Mr. Williams) I will ask you to keep Exhibit No. 5</p> <p>10 nearby.</p> <p>11 Exhibit No. 6, I will represent to you, is the CUP</p> <p>12 panel web page, which we printed out on January 7th,</p> <p>13 2019.</p> <p>14 Are you pictured in the picture there?</p> <p>15 A Yes.</p> <p>16 Q Is that you five people over from the right?</p> <p>17 A Yes.</p> <p>18 Q Above the photo that you appear in, do you see where it</p> <p>19 says, "In 2018 the expert panel, chaired by Professor</p> <p>20 Alan Jackson, issued our latest cancer prevention</p> <p>21 recommendations as part of the World Cancer Research</p> <p>22 Fund/American Institute for Cancer Research third expert</p> <p>23 report, 'Diet, nutrition, physical activity and cancer: a</p> <p>24 global perspective."</p> <p>25 That's what it says, correct?</p>	<p style="text-align: right;">Page 85</p> <p>1 I've counted. There are now nine panelists as of</p> <p>2 2018, and you are listed as one, correct?</p> <p>3 A You are looking at-- sorry, which?</p> <p>4 Q Page 21 of Exhibit No. 5.</p> <p>5 Do you see it listed there on Page 21?</p> <p>6 A Yes.</p> <p>7 Q Now, please go back to Page 6 of Exhibit No. 5, the 2018</p> <p>8 report of the World Cancer Research Fund.</p> <p>9 Under the box "Summary of panel judgments," do you</p> <p>10 see there that the same conclusions that were set forth</p> <p>11 in the 2014 report concerning the panel judgments are set</p> <p>12 forth?</p> <p>13 A So you are talking about this table--</p> <p>14 Q If you look in the lower left-hand corner of the page, it</p> <p>15 has Page No. 6.</p> <p>16 Are you looking at the 2018--</p> <p>17 A It says, "Summary of panel judgments."</p> <p>18 Q Correct, and do you see the box that's underneath there</p> <p>19 with subheadings?</p> <p>20 A Yeah.</p> <p>21 One thing to point out is that this table, which is</p> <p>22 the summary-- so you are in Exhibit No. 5 ? It says,</p> <p>23 "2014," so it's the exact same as this 2014 report.</p> <p>24 Q Ma'am, I am not even looking at that page.</p> <p>25 A Okay.</p>

22 (Pages 82 to 85)

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<p style="text-align: right;">Page 86</p> <p>1 Q I am asking you to look at Page 6.</p> <p>2 A Page 6.</p> <p>3 Q Which says, "The summary of the panel judgments."</p> <p>4 A Okay.</p> <p>5 Q In that summary of the panel judgments it sets forth the</p> <p>6 same conclusions that were contained in the 2014 report</p> <p>7 regarding linear growth, body fatness, and lactation,</p> <p>8 correct?</p> <p>9 A That's correct.</p> <p>10 Q There's no reference to talcum powder here either,</p> <p>11 correct?</p> <p>12 A That's correct.</p> <p>13 Q As of 2018 you had been retained as an expert by the</p> <p>14 plaintiffs' lawyers in this litigation; is that correct?</p> <p>15 MS. PARFITT: Objection; form.</p> <p>16 THE WITNESS: The summaries are</p> <p>17 regarding the data analyzed by WCRF on nutrition</p> <p>18 variables.</p> <p>19 They do not consider-- they do not do systematic</p> <p>20 reviews for other ovarian cancer risk factors, only</p> <p>21 nutrition variables.</p> <p>22 Q (By Mr. Williams) Let me ask you to go to Page 3.</p> <p>23 Again in your last answer you said "they."</p> <p>24 You are a panelist for this organization, correct?</p> <p>25 A Yes, I am a panelist, but I don't-- I am not in a</p>	<p style="text-align: right;">Page 88</p> <p>1 in 2018, which is after you had been retained by</p> <p>2 plaintiff lawyers to opine on whether or not talc could</p> <p>3 cause ovarian cancer, true or not true?</p> <p>4 MS. PARFITT: Objection; form, asked</p> <p>5 and answered.</p> <p>6 THE WITNESS: I want to be able to</p> <p>7 answer this to try to make it more clear.</p> <p>8 If you see on the cover, it says, "2014."</p> <p>9 This is the 2014 report that was added to all of the</p> <p>10 other reports.</p> <p>11 Some were developed in 2011, some in 2017.</p> <p>12 We did not redo the meta-analyses. We did not redo</p> <p>13 the entire report.</p> <p>14 They were added together.</p> <p>15 The World Cancer Research Fund for the first two</p> <p>16 reports did all of the work at one time and came up with</p> <p>17 books, so the most recent one was 2007.</p> <p>18 This time they decided to do reports on a rolling</p> <p>19 basis. That's why Ovarian came out in 2014, but that</p> <p>20 their final-- when they put it all together, they</p> <p>21 celebrate, come out with big systematic-- sorry, summary</p> <p>22 guidelines for the public for preventing cancer-related</p> <p>23 nutrition, physical activity, things that people can do--</p> <p>24 that was all added together in 2018, but this ovarian</p> <p>25 report was from 2014.</p>
<p style="text-align: right;">Page 87</p> <p>1 position to choose what WCRF decides to contract out for</p> <p>2 analyses.</p> <p>3 They contract with the Imperial College of what the</p> <p>4 focus is going to be: nutrition, physical activity, diet.</p> <p>5 It's my-- I have the ability to refuse to be on the</p> <p>6 panel, to decline if I don't want to be involved with</p> <p>7 nutrition, physical activity, and obesity research</p> <p>8 because that's the mission. The mission are those</p> <p>9 variables, not to do systematic reviews on other risk</p> <p>10 factors.</p> <p>11 We don't do anything on cigarette smoking or other</p> <p>12 types of carcinogens, for example.</p> <p>13 We only do nutrition, physical activity,</p> <p>14 obesity-related variables.</p> <p>15 Q To be clear, this CUP update on ovarian cancer came out</p> <p>16 in 2018, which is after you were retained by plaintiff</p> <p>17 lawyers to opine on whether or not talc could cause</p> <p>18 ovarian cancer.</p> <p>19 Is that true or not true?</p> <p>20 MS. PARFITT: Objection; form, asked</p> <p>21 and answered.</p> <p>22 Q (By Mr. Williams) I am looking for a temporal answer.</p> <p>23 This--</p> <p>24 MS. PARFITT: Same objection.</p> <p>25 Q (By Mr. Williams) This update on ovarian cancer came out</p>	<p style="text-align: right;">Page 89</p> <p>1 MR. WILLIAMS: I will move to strike</p> <p>2 that as nonresponsive.</p> <p>3 Q (By Mr. Williams) Dr. McTiernan, on the first page of</p> <p>4 this document it says it was revised in 2018.</p> <p>5 This document that's in front of you now was</p> <p>6 published in 2018, wasn't it?</p> <p>7 MS. PARFITT: Objection; form.</p> <p>8 She has been asked and answered it.</p> <p>9 You have limited time, Mr. Williams, so I suggest</p> <p>10 you listen to her answer.</p> <p>11 Q (By Mr. Williams) This document was published in 2018,</p> <p>12 yes or no?</p> <p>13 MS. PARFITT: Objection; form, asked</p> <p>14 and answered.</p> <p>15 THE WITNESS: This document was</p> <p>16 published along with all of the other documents, but the</p> <p>17 document was prepared in 2014.</p> <p>18 It's a report in 2014.</p> <p>19 Q (By Mr. Williams) What year was this document published?</p> <p>20 MS. PARFITT: The document speaks for</p> <p>21 itself. Objection; form.</p> <p>22 THE WITNESS: It says, "Revised 2018."</p> <p>23 Q (By Mr. Williams) 2018 was after you were retained by</p> <p>24 Plaintiffs' counsel, correct?</p> <p>25 MS. PARFITT: Objection; form,</p>

23 (Pages 86 to 89)

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<p style="text-align: right;">Page 90</p> <p>1 mischaracterizes her testimony.</p> <p>2 Q (By Mr. Williams) You may answer, Doctor.</p> <p>3 MS. PARFITT: Objection; form.</p> <p>4 Answer as best you can.</p> <p>5 THE WITNESS: Yes, 2018 is after I was</p> <p>6 retained.</p> <p>7 Q (By Mr. Williams) It was a couple years after you had</p> <p>8 been retained, right?</p> <p>9 A That's correct.</p> <p>10 Q Could you list for me all of the members of the panel who</p> <p>11 served with you on the World Cancer Research Fund whom</p> <p>12 you told, "We need to update this to state that talc,</p> <p>13 which is something that people can use or not use, is</p> <p>14 something that they should not use because it causes</p> <p>15 ovarian cancer"?</p> <p>16 List for me the people who are listed on Page 21, as</p> <p>17 fellow panel members, all of the people that you have</p> <p>18 told that.</p> <p>19 A I didn't talk with others about other risk factors for</p> <p>20 ovarian cancer because we were using the same report</p> <p>21 unchanged from 2014.</p> <p>22 Q Is the answer that there's no one?</p> <p>23 MS. PARFITT: Objection; misstates her</p> <p>24 testimony.</p> <p>25 Q (By Mr. Williams) Is the answer that there is no one</p>	<p style="text-align: right;">Page 92</p> <p>1 This says, "Our cancer prevention recommendations."</p> <p>2 When it says "our" there, that refers to the panel</p> <p>3 on which you sat in 2018, correct?</p> <p>4 A This is correct.</p> <p>5 This is a separate document.</p> <p>6 It must have been from the ovarian report because</p> <p>7 this is-- there are separate recommendations based on all</p> <p>8 of the cancers.</p> <p>9 Q The panel does not recommend limiting or stopping the use</p> <p>10 of talcum powder, correct?</p> <p>11 A The panel did not look at all potential carcinogens.</p> <p>12 The panel looked and developed recommendations based</p> <p>13 on nutrition, physical activity, and obesity-related</p> <p>14 variables.</p> <p>15 Q Is the answer that it does not list talc?</p> <p>16 MS. PARFITT: Objection; form.</p> <p>17 THE WITNESS: It does not list talc,</p> <p>18 but it doesn't list other carcinogens as well.</p> <p>19 Q (By Mr. Williams) Please turn to Page 8.</p> <p>20 I am referring to Page 8 of the 2018 CUP report.</p> <p>21 I will direct your attention to Section 4 at the top</p> <p>22 that says, "Other established causes."</p> <p>23 Do you see that?</p> <p>24 A Yes.</p> <p>25 Q Not bearing children is listed as something that may be</p>
<p style="text-align: right;">Page 91</p> <p>1 there?</p> <p>2 MS. PARFITT: Objection; form,</p> <p>3 misstates her testimony.</p> <p>4 Q (By Mr. Williams) You may answer.</p> <p>5 A Correct.</p> <p>6 MS. PARFITT: You may answer.</p> <p>7 Q (By Mr. Williams) Is the answer correct?</p> <p>8 A Correct.</p> <p>9 MS. PARFITT: Objection.</p> <p>10 MR. WILLIAMS: Counsel, I am entitled</p> <p>11 to an answer to the question.</p> <p>12 MS. PARFITT: You can, and I'm</p> <p>13 entitled to object to the form.</p> <p>14 MR. WILLIAMS: But you are objecting</p> <p>15 over her answer.</p> <p>16 MS. PARFITT: No, I am objecting-- she</p> <p>17 is answering quite quickly. I am trying to object before</p> <p>18 she answers, but after you.</p> <p>19 MR. WILLIAMS: Fair enough.</p> <p>20 MS. PARFITT: Thanks.</p> <p>21 Q (By Mr. Williams) Please turn to the second-to-last page</p> <p>22 of this 2018 CUP report, which is entitled, "Our cancer</p> <p>23 prevention recommendations."</p> <p>24 It is a purple page. It is the inside cover of the</p> <p>25 pamphlet.</p>	<p style="text-align: right;">Page 93</p> <p>1 seen as a cause of ovarian cancer, correct?</p> <p>2 A Correct.</p> <p>3 Q Early menarche or age of first period is listed as</p> <p>4 something that your panel concluded may be seen as a</p> <p>5 cause of ovarian cancer, true?</p> <p>6 A It wasn't a panel conclusion. We weren't asked to judge</p> <p>7 data.</p> <p>8 This was written up as a background for other</p> <p>9 potential causes.</p> <p>10 There were no data that was reviewed by the panel.</p> <p>11 Q The heading is, "Other established causes," right?</p> <p>12 A Right.</p> <p>13 WCRF prefers to use that language. I'm not sure I</p> <p>14 would have used that.</p> <p>15 Q Talc is not listed as an established cause, correct?</p> <p>16 A It is not.</p> <p>17 It looks like the paragraph was unchanged from 2014.</p> <p>18 It was not updated.</p> <p>19 This report, from my knowledge, is the same in 2014</p> <p>20 as this-- as what's called "Revised," but I believe it's</p> <p>21 the same report.</p> <p>22 Q Did you, as a member of this expert panel, conclude that</p> <p>23 talc could be seen as a cause of ovarian cancer?</p> <p>24 A This expert panel didn't consider talc.</p> <p>25 Q Is the answer "no?"</p>

24 (Pages 90 to 93)

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<p style="text-align: right;">Page 94</p> <p>1 MS. PARFITT: Objection; form--</p> <p>2 THE WITNESS: All I can say is we</p> <p>3 didn't consider-- we didn't review the literature. We</p> <p>4 didn't do-- review any of these other variables in</p> <p>5 totality.</p> <p>6 Q (By Mr. Williams) Is there any reason why you don't do</p> <p>7 that?</p> <p>8 A We were tasked at looking at nutrition, physical</p> <p>9 activity, and obesity-related variables.</p> <p>10 Q Tasked by whom?</p> <p>11 A By WCRF, World Cancer Research Fund.</p> <p>12 Q Did the World Cancer Research Fund say that you could not</p> <p>13 look into talc?</p> <p>14 MS. PARFITT: Objection; form.</p> <p>15 THE WITNESS: They did-- in our</p> <p>16 personal lives, that we could look into any variable you</p> <p>17 wanted to, but for this purpose of this panel, we were</p> <p>18 only looking at and evaluating the meta-analysis, which</p> <p>19 was focused on physical activity, diet, and nutrition</p> <p>20 variables.</p> <p>21 Q (By Mr. Williams) Let me ask you to turn to Page 7 of</p> <p>22 the CUP report.</p> <p>23 A Which one?</p> <p>24 Q Page 7 of the 2018 report, Exhibit No. 5.</p> <p>25 A Okay.</p>	<p style="text-align: right;">Page 96</p> <p>1 cancers.</p> <p>2 "Spontaneous" means something else caused it.</p> <p>3 Q However you define "spontaneous," do you agree that most</p> <p>4 ovarian cancers occur spontaneously?</p> <p>5 MS. PARFITT: Objection; form.</p> <p>6 THE WITNESS: I agree that most-- I</p> <p>7 would not use that word myself because it can be</p> <p>8 misconstrued by nonscientists.</p> <p>9 "Spontaneous" means "nongenetically inherited," so I</p> <p>10 would say environmental, that most cancers-- most ovarian</p> <p>11 cancers are caused by something in the environment, some</p> <p>12 exposure.</p> <p>13 Q (By Mr. Williams) Did you tell someone to take out the</p> <p>14 word "spontaneously"?</p> <p>15 A I don't recall.</p> <p>16 We did have an opportunity in 2014 to edit these</p> <p>17 various reports.</p> <p>18 None of us had final say on exactly what came out of</p> <p>19 the report.</p> <p>20 We did go through a process of editing.</p> <p>21 Q When you had the opportunity to edit the report in 2014,</p> <p>22 did you ask someone to take out the word "spontaneously"?</p> <p>23 A I don't recall.</p> <p>24 Q When you say you don't recall, are you saying it may have</p> <p>25 happened, it may not have happened?</p>
<p style="text-align: right;">Page 95</p> <p>1 Q Do you see the heading that says, "Pathogenesis"?</p> <p>2 A Yes.</p> <p>3 Q Do you see where in the second paragraph the panel</p> <p>4 concluded that the-- quote, "Most ovarian cancers occur</p> <p>5 spontaneously, although five to ten percent of cases</p> <p>6 develop due to a genetic disposition," Closed quote?</p> <p>7 Do you see that?</p> <p>8 A I see that, and above that I see that "The epithelial</p> <p>9 cells are subjected to a unique pro-inflammatory</p> <p>10 microenvironment, which can increase the rate of DNA</p> <p>11 damage, thus affecting cancer risk."</p> <p>12 In this case the word "spontaneous" just means "as</p> <p>13 opposed to genetics."</p> <p>14 Spontaneous cancers mean they can be caused by</p> <p>15 anything else, including environment, but not solely due</p> <p>16 to an inherited genetic predisposition.</p> <p>17 Q Do you agree that most ovarian cancers occur</p> <p>18 spontaneously?</p> <p>19 A I believe most are caused by environmental causes as for</p> <p>20 many other cancers.</p> <p>21 I am using the word "spontaneous." I mean "non</p> <p>22 solely genetic."</p> <p>23 Cancer is a genetic disease, but the familial</p> <p>24 genetic-inherited cancers account for only about five to</p> <p>25 ten percent of ovarian cancers, similar to many other</p>	<p style="text-align: right;">Page 97</p> <p>1 A It may have happened, it may not.</p> <p>2 I apologize, I don't recall.</p> <p>3 Q And after you make such a recommendation as a panelist,</p> <p>4 who decides what gets put in?</p> <p>5 A The World Cancer Research Fund. The scientific officers</p> <p>6 would decide.</p> <p>7 Q They would listen to the input and then decide one way or</p> <p>8 the other?</p> <p>9 A Yes.</p> <p>10 Q In 2014 the Gertig 2000 and Terry 2013 studies on talc,</p> <p>11 that you reviewed in 2016, had already been published,</p> <p>12 correct?</p> <p>13 A I am hesitating because I don't remember when this exact</p> <p>14 writing was.</p> <p>15 If it's a 2014 report, that's when it came out.</p> <p>16 It could have been being written within 2013, so at</p> <p>17 the time I was not doing research on all of the variables</p> <p>18 related to ovarian cancer, so I can't say what was</p> <p>19 published at that time.</p> <p>20 Q 2014 is after 2013, correct?</p> <p>21 A That's correct.</p> <p>22 Q If Gertig was published in 2000, Gertig would have been</p> <p>23 published prior to the time that this exhibit, the 2014</p> <p>24 version of this exhibit, was published, correct?</p> <p>25 A Published but perhaps not when it was prepared, that's</p>

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<p>1 what I'm saying.</p> <p>2 Q If the Terry study was published in 2013, it would have</p> <p>3 been published prior to the time that the 2014 version of</p> <p>4 the World Cancer Research Fund would have been published,</p> <p>5 correct?</p> <p>6 A It would have been published prior to publication, not</p> <p>7 necessarily prior to report preparation.</p> <p>8 Q Have you ever been on the World Cancer Research Fund web</p> <p>9 page?</p> <p>10 A Yes, I have.</p> <p>11 Q Let me show you what we've marked as Exhibit No. 7 or</p> <p>12 what we will mark as Exhibit No. 7 to your deposition.</p> <p>13 (Exhibit No. 7 marked</p> <p>14 for identification.)</p> <p>15</p> <p>16 Q (By Mr. Williams) Exhibit No. 7 is the World Cancer</p> <p>17 Research Fund web page.</p> <p>18 We printed this out as of January 8th, 2019.</p> <p>19 It's a five-page document, and the portion that we</p> <p>20 printed out is "Myths and controversies about what causes</p> <p>21 cancer."</p> <p>22 Do you see that?</p> <p>23 A Yes, I do.</p> <p>24 Q There is only one World Cancer Research Fund, to your</p> <p>25 knowledge, correct?</p>	<p>1 if you are trying to get to the World Cancer Research</p> <p>2 Fund website.</p> <p>3 Will you accept that representation, ma'am?</p> <p>4 A It looks like it comes from their website.</p> <p>5 I am not clear on who developed this or-- it</p> <p>6 certainly didn't have oversight by our committee.</p> <p>7 Our committee was tasked at looking at the data from</p> <p>8 the meta-analysis and systematic review.</p> <p>9 None of these variables-- none of the variables</p> <p>10 here, except perhaps coffee, were considered by my panel.</p> <p>11 My panel does not oversee all World Cancer Research</p> <p>12 Fund. There are other groups that oversee them.</p> <p>13 I do not.</p> <p>14 I oversee-- sorry, I participate on one panel that</p> <p>15 focuses on nutrition, physical activity, and diet</p> <p>16 meta-analyses.</p> <p>17 Q Take a look at Page 2 of this document, which is Exhibit</p> <p>18 No. 7.</p> <p>19 At the top of the page it says, "Cosmetics and</p> <p>20 toiletries."</p> <p>21 Do you see that?</p> <p>22 A I do.</p> <p>23 Q It says, "Most studies have found no link between cancer</p> <p>24 and the chemicals used in cosmetic and toiletry products,</p> <p>25 such as moisturizers, shampoos, deodorants, and</p>
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<p>1 A That's correct.</p> <p>2 Q The World Cancer Research Fund, the organization for whom</p> <p>3 you have served as an advisory panel member for years,</p> <p>4 tries to advise the public about potential causes for</p> <p>5 cancer, correct?</p> <p>6 MS. PARFITT: Objection; form.</p> <p>7 THE WITNESS: Their focus is on</p> <p>8 nutrition, physical activity, and obesity variables.</p> <p>9 That's what they advise on. That's what their</p> <p>10 recommendations are.</p> <p>11 Q (By Mr. Williams) The World Cancer Research Fund tries</p> <p>12 to debunk myths about what has been established as a</p> <p>13 cause of cancer, correct?</p> <p>14 MS. PARFITT: Objection; form.</p> <p>15 THE WITNESS: Before I answer that, I</p> <p>16 would like to know if this is a Blount post.</p> <p>17 If it's not-- it's not something that has come</p> <p>18 before the World Cancer Research Fund.</p> <p>19 We would never investigate or were never asked to</p> <p>20 comment on these particular issues.</p> <p>21 Q (By Mr. Williams) I will represent to you that the</p> <p>22 address that is listed at the bottom of the page, which</p> <p>23 includes</p> <p>24 www.wcrf-uk.org/uk/preventing-cancer/cancer-risk-factors-</p> <p>25 and it goes on, is, in fact, where you get-- where you go</p>	<p>1 toothpastes. The majority of countries have strict</p> <p>2 regulations to ensure these products are safe."</p> <p>3 Do you see that?</p> <p>4 A Yes.</p> <p>5 Q It goes on, second paragraph, "Some studies have found a</p> <p>6 link between talcum powder, talc, and ovarian cancer, but</p> <p>7 there is not enough evidence to be certain of this. Even</p> <p>8 if there were an increased risk, scientists estimate it</p> <p>9 would be small. Not smoking, followed by maintaining a</p> <p>10 healthy weight through eating a healthy diet and keeping</p> <p>11 active, are the most effective ways to reduce your cancer</p> <p>12 risk."</p> <p>13 Did I read that right?</p> <p>14 A Yes, you did.</p> <p>15 Q Do you disagree with that statement of the World Cancer</p> <p>16 Research Fund?</p> <p>17 A I do.</p> <p>18 I am surprised it's there.</p> <p>19 Q Is it accurate to say that your opinion in this case that</p> <p>20 the state of known scientific evidence establishes that</p> <p>21 perineal use of talc causes ovarian cancer conflicts with</p> <p>22 the conclusion set forth on the website of the World</p> <p>23 Cancer Research Fund that there is not enough evidence to</p> <p>24 be certain that there is a link between talcum powder use</p> <p>25 and ovarian cancer?</p>

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<p style="text-align: right;">Page 102</p> <p>1 MS. PARFITT: Objection; form,</p> <p>2 misstates the document.</p> <p>3 THE WITNESS: I do disagree.</p> <p>4 Q (By Mr. Williams) Your opinion in this case conflicts</p> <p>5 with the--</p> <p>6 A Yes, my opinion conflicts--</p> <p>7 Q You need to wait until I'm done, ma'am if you would.</p> <p>8 A Okay.</p> <p>9 Q Your opinion in this case, as set forth in your report,</p> <p>10 conflicts with the conclusions set forth specifically</p> <p>11 regarding talcum powder on the World Cancer Research Fund</p> <p>12 website, correct?</p> <p>13 MS. PARFITT: Objection to the form.</p> <p>14 THE WITNESS: Yes, that's correct.</p> <p>15 Q (By Mr. Williams) The American Institute for Cancer</p> <p>16 Research tries to advise the public regarding potential</p> <p>17 causes of cancer; is that right?</p> <p>18 MS. PARFITT: Objection; form,</p> <p>19 misstates her testimony.</p> <p>20 THE WITNESS: The American Institute</p> <p>21 for Cancer Research is part of the World Cancer Research</p> <p>22 Foundation, and they have the same mission, to focus on</p> <p>23 nutrition, physical activity, and obesity in relation to</p> <p>24 cancer risk and survival.</p> <p>25 Q (By Mr. Williams) Did you know that the American</p>	<p style="text-align: right;">Page 104</p> <p>1 A Yes.</p> <p>2 Q And the second paragraph that's listed there on Exhibit</p> <p>3 No. 8 is identical to the paragraph that we just went</p> <p>4 over in Exhibit No. 7 relating to talcum powder and</p> <p>5 ovarian cancer; is that right?</p> <p>6 A Yes, I see that.</p> <p>7 Q Is it accurate to say that your opinion in this case,</p> <p>8 that the state of known scientific evidence establishes</p> <p>9 that perineal use of talc causes ovarian cancer,</p> <p>10 conflicts with the conclusion of the American Institute</p> <p>11 for Cancer Research, that there is not enough evidence to</p> <p>12 be certain that there is a link between talc use and</p> <p>13 ovarian cancer?</p> <p>14 MS. PARFITT: Objection; form.</p> <p>15 THE WITNESS: Yes, I disagree with</p> <p>16 what they have written here.</p> <p>17 Q (By Mr. Williams) You have never told anyone from the</p> <p>18 AICR, I take it, that you disagree?</p> <p>19 MS. PARFITT: Objection; form.</p> <p>20 THE WITNESS: I did not know that they</p> <p>21 had this on their website.</p> <p>22 I think I will talk to them now.</p> <p>23 Q (By Mr. Williams) Let me direct your attention to a new</p> <p>24 document, which is an article from Hutch News that refers</p> <p>25 to you.</p>
<p style="text-align: right;">Page 103</p> <p>1 Institute for Cancer Research includes a page on its</p> <p>2 website discussing whether different exposures can cause</p> <p>3 cancer?</p> <p>4 A I would have to see it, but no, I do not follow whatever</p> <p>5 page you're talking about.</p> <p>6 I don't know what you're referring to.</p> <p>7 (Exhibit No. 8 marked</p> <p>8 for identification.)</p> <p>9</p> <p>10 Q (By Mr. Williams) Let me show you what we've marked as</p> <p>11 Exhibit No. 8.</p> <p>12 Exhibit No. 8 is a three-page document, which is a</p> <p>13 printout of the website of the AICR. The address is</p> <p>14 listed at the bottom of Page 1 of Exhibit No. 8.</p> <p>15 You are familiar with the American Institute for</p> <p>16 Cancer Research?</p> <p>17 A Yes, I am.</p> <p>18 It is a part of the World Cancer Research Fund.</p> <p>19 Q I would like you to look at the first page of Exhibit</p> <p>20 No. 8.</p> <p>21 There is a listing that says, "GMOs and other hot</p> <p>22 topics," and then there are seven different topics that</p> <p>23 are set forth, the fifth of which is cosmetics and</p> <p>24 toiletries.</p> <p>25 Do you see that?</p>	<p style="text-align: right;">Page 105</p> <p>1 We'll mark it as Exhibit No. 9.</p> <p>2 (Exhibit No. 9 marked</p> <p>3 for identification.)</p> <p>4</p> <p>5 Q (By Mr. Williams) This is an article that was published</p> <p>6 on May 25th, 2018, correct?</p> <p>7 It's a commentary written by you?</p> <p>8 A Yes. It was edited by-- our communications department</p> <p>9 edited it, so I authored it, but they adjusted it.</p> <p>10 Q May 25, 2018 was at least a year and a half after you had</p> <p>11 been retained by plaintiffs' counsel for this engagement,</p> <p>12 correct?</p> <p>13 MR. LOCKE: We haven't seen Exhibit</p> <p>14 No.--</p> <p>15 Q (By Mr. Williams) Did you hear my question?</p> <p>16 A No-- yes.</p> <p>17 Q You're quoted in this article-- strike that.</p> <p>18 The title of your article is, "How to reduce the</p> <p>19 odds of getting cancer," right?</p> <p>20 A Yes.</p> <p>21 Q You are quoted in this article as saying there are steps</p> <p>22 people can take to absolutely cut their risk of getting</p> <p>23 cancer, true?</p> <p>24 A Yes.</p> <p>25 Q Directly under the title there's a quote that says,</p>

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<p style="text-align: right;">Page 106</p> <p>1 "There are steps you can take that will absolutely cut 2 your risk, says Fred Hutch's doctor Anne McTiernan, who 3 contributed to a new report on diet, nutrition, physical 4 activity and cancer," did I read that right? 5 A Yes. 6 Q Now, at the time that you were writing this commentary, I 7 take it that you were not limited in any way in what you 8 could talk about as a way that someone could cut their 9 risk of getting cancer? 10 No one was editing your words, true? 11 A That's not true. 12 The communications department has final say on what 13 goes out from our institution, so I don't have full 14 leeway of what went out. 15 They had asked me to write about something, with 16 their help, their editing, on the new report by the World 17 Cancer Research Fund, so it focused primarily on 18 nutrition, physical activity, and diet information. 19 Q Are you suggesting that you could not have referenced 20 talcum powder or stopping the use of talcum powder as it 21 relates to your view of ovarian cancers, ma'am? 22 A I am saying I was asked to focus on these variables in 23 this new report. 24 Fred Hutchinson is-- the communications department 25 is a news program-- sorry, a news service-- they call</p>	<p style="text-align: right;">Page 108</p> <p>1 MS. PARFITT: Objection; form. 2 THE WITNESS: When we do a causation 3 analysis as epidemiologists, we primarily rely on results 4 in humans and especially epidemiology, but we also look 5 to see if there are plausible biologic mechanisms that 6 can link what we see in the human data, in terms of 7 exposure to risk of disease, so we do look at biological 8 mechanisms as well. 9 Q (By Mr. Williams) Much of epidemiologic observational 10 research in cancer focuses on determining the 11 associations between an exposure and an outcome, true or 12 not true? 13 A Yes, that's true. 14 Q The mere existence of an association does not itself 15 prove a cause and effect relationship between the 16 exposure and the disease, right? 17 A The existence of an association is typically part of the 18 scientific data we would use in order to determine if 19 it's a cause and effect, and there could be some-- some 20 associations that would be so difficult to explain 21 otherwise, that you would understand that that has to be 22 a cause, but typically in the epidemiology of cancer, we 23 are looking at both the results in human, human 24 population studies, epidemiology studies, but we also 25 look at plausible biologic mechanisms.</p>
<p style="text-align: right;">Page 107</p> <p>1 themselves a news service, and they wanted me to talk 2 about new results. 3 I added-- I did add to try to avoid other 4 carcinogens, and I specifically mentioned air pollution 5 and asbestos as some things that affect many different 6 cancers, but I was primarily tasked to talk about 7 nutrition, physical activity, and diet, and especially 8 since that was a new report. 9 That's why this article is focused on that. 10 Q Did you identify talc use as an actual or probable 11 carcinogen of any kind of cancer in this article? 12 A This was not focused on any particular risk factor, so I 13 was talking about very generic environmental causes of 14 cancer, and I can see that I did mention asbestos as an 15 example, but I did not list all of the cancer-causing 16 chemicals that can be encountered. 17 Q In terms of your day-to-day research activities, those 18 are in the field of epidemiology, correct? 19 A Epidemiology and clinical trials. 20 Some people consider that clinical research, and 21 some consider it epidemiology, but I'm an epidemiologist 22 and an internist. 23 Q When it comes to assessing cause, epidemiology, your 24 field, is only one part of the causation analysis; is 25 that true?</p>	<p style="text-align: right;">Page 109</p> <p>1 Q Association is not synonymous with causation, is it, 2 ma'am? 3 A Association, correct, it's not exactly the same as 4 causation. 5 Q As you read the epidemiologic literature as part of your 6 work in this matter, you considered the Bradford Hill 7 aspects of causal inference, right? 8 A That's correct. 9 Q The continuous research project, for which you serve as a 10 panel member, also uses the Bradford Hill criteria as the 11 basis for its systematic review analyses, true? 12 A The World Cancer Research Fund has a modified version of 13 Bradford Hill. 14 Most groups that are looking at these types of 15 variables, and are looking at developing public 16 recommendations, will use some kind of modification of 17 Bradford-Hill-like criteria, so the World Cancer Research 18 Fund has developed criteria that are very different in 19 some way from other epidemiology studies, and 20 particularly because they're focused on nutrition, and 21 nutrition is a variable different from other types of 22 exposures in terms of developing them. 23 They also have further developed those criteria for 24 survivorship, so it's not exactly a Bradford Hill 25 analysis.</p>

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<p>1 Q The Bradford Hill criteria are the basis for the</p> <p>2 Continuous Update Project systematic review analyses and</p> <p>3 the criteria for judging the evidence, true or not true?</p> <p>4 MS. PARFITT: Objection; form, asked</p> <p>5 and answered.</p> <p>6 THE WITNESS: I would say Bradford</p> <p>7 Hill criteria were considered in developing the</p> <p>8 guidelines for the systematic review interpretation.</p> <p>9 (Exhibit No. 10 marked</p> <p>10 for identification.)</p> <p>11</p> <p>12 Q (By Mr. Williams) Let me have you look at what we've</p> <p>13 marked as Exhibit No. 10.</p> <p>14 Exhibit No. 10 is a multi-page document from the</p> <p>15 World Cancer Research Fund entitled, "Judging the</p> <p>16 evidence," and dated 2018.</p> <p>17 Do you recognize this document?</p> <p>18 A Yes, I do.</p> <p>19 Q This document was published at a time when you were</p> <p>20 serving as a panelist for the World Cancer Research Fund?</p> <p>21 A It was developed before then, but it was published again</p> <p>22 at that time, yes.</p> <p>23 Q Let me have you look at Page 4.</p> <p>24 Page 4 sets forth how to cite the third expert</p> <p>25 report ; does it not?</p>	<p>1 That was my question.</p> <p>2 MS. PARFITT: Mr. Williams, if I could</p> <p>3 just say, she is a doctor, if we could refer to her as</p> <p>4 "Doctor."</p> <p>5 MR. WILLIAMS: I'm sorry. Pardon me.</p> <p>6 Q (By Mr. Williams) Dr. McTiernan, excuse me, is that last</p> <p>7 sentence of the second paragraph on Page 5 accurate or</p> <p>8 not?</p> <p>9 MS. PARFITT: Thank you.</p> <p>10 Objection.</p> <p>11 THE WITNESS: When I said "basis," I</p> <p>12 would say it's the beginning because it was revised quite</p> <p>13 a bit.</p> <p>14 I will add to that.</p> <p>15 There are things in this document, in this</p> <p>16 evidence-- "Judging the evidence" document that go much</p> <p>17 beyond what Bradford Hill aspects considered and are much</p> <p>18 more specific to these types of variables.</p> <p>19 Q (By Mr. Williams) Let me have you turn to-- let's take a</p> <p>20 look back at the exhibit that we marked as Exhibit No. 5.</p> <p>21 Exhibit No. 5 is the 2018 revised report.</p> <p>22 Do you have that in front of you?</p> <p>23 A Yes.</p> <p>24 Q This document at Page 9 sets forth the methodology for</p> <p>25 the report.</p>
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<p>1 A How to cite the whole report, yes.</p> <p>2 Q It was contemplated at the time that this document,</p> <p>3 "Judging the evidence," was published, that it could be</p> <p>4 cited by experts, correct?</p> <p>5 MS. PARFITT: Objection; form.</p> <p>6 THE WITNESS: Yes.</p> <p>7 Q (By Mr. Williams) Look at Page 5, if you would.</p> <p>8 A (Witness complies.)</p> <p>9 Q Page 5 under the title, "Introduction," the second full</p> <p>10 paragraph, I will direct you to the last sentence. It</p> <p>11 says, "The Bradford Hill criteria are the basis for the</p> <p>12 Continuous Update Project, CUP, systematic review</p> <p>13 analyses and the criteria for judging evidence."</p> <p>14 Do you see that?</p> <p>15 A Yes, I do.</p> <p>16 Q Is that an accurate statement?</p> <p>17 A I would say it's the beginning because they did change,</p> <p>18 and it spanned quite a bit compared to Bradford Hill.</p> <p>19 Bradford Hill's speech, when he developed it and</p> <p>20 when the result was published in the World Society of</p> <p>21 Medicine, was very basic, did not have the many criteria</p> <p>22 that World Cancer Research Fund uses, and their criteria,</p> <p>23 the way they developed it, beyond Bradford Hill, was</p> <p>24 because of the nutrition-related variables.</p> <p>25 Q Is it an accurate statement or not, ma'am?</p>	<p>1 Do you see that on Page 9?</p> <p>2 A Yes.</p> <p>3 Q And it says, "Through this process," and this is the</p> <p>4 third paragraph on that page. "Through this process the</p> <p>5 CUP ensures that everyone, including policy-makers,</p> <p>6 health professionals, and members of the public, has</p> <p>7 access to the most up-to-date information on how to</p> <p>8 reduce the risk of developing cancer."</p> <p>9 Do you see that?</p> <p>10 A No-- so you are on Page 9?</p> <p>11 Which paragraph?</p> <p>12 Q I'm sorry, Page 4. I misspoke.</p> <p>13 MS. PARFITT: Thank you.</p> <p>14 Q (By Mr. Williams) Pardon me, ma'am-- Doctor.</p> <p>15 Page 4, third paragraph, under "Our Continuous</p> <p>16 Update Project."</p> <p>17 Do you see that?</p> <p>18 A Yes.</p> <p>19 Q The whole purpose of the continuous update process is to</p> <p>20 try to ensure that members of the public have access to</p> <p>21 the most up-to-date information on how to reduce the risk</p> <p>22 of developing cancer, correct?</p> <p>23 MS. PARFITT: Objection; misstates the</p> <p>24 document.</p> <p>25 THE WITNESS: If you are looking at</p>

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<p style="text-align: right;">Page 114</p> <p>1 that sentence, you would also have to put it in context</p> <p>2 of what this report is.</p> <p>3 It's related to diet, nutrition, physical activity</p> <p>4 and cancer.</p> <p>5 It is not all potential causes of cancer that an</p> <p>6 individual could modify in order to reduce risk.</p> <p>7 We are talking only about diet, nutrition, and</p> <p>8 physical activity.</p> <p>9 Q (By Mr. Williams) Let's look at Page No. 9 of this</p> <p>10 exhibit.</p> <p>11 At the end of the first paragraph, under the</p> <p>12 heading, "Methodology," it says, halfway down that</p> <p>13 paragraph, "The literature search was restricted to</p> <p>14 Medline and included only randomized controlled trials,</p> <p>15 cohort and case-control studies. Due to their</p> <p>16 methodological limitations, case-control studies were not</p> <p>17 analyzed in the Ovarian Cancer SLR 2013."</p> <p>18 Do you see that?</p> <p>19 A Yes.</p> <p>20 Q And "SLR" refers to "systematic literature review"?</p> <p>21 A Yes, it does.</p> <p>22 Q When you were considering the literature in your work for</p> <p>23 the World Cancer Research Fund to determine what causes</p> <p>24 cancer, it is accurate that your panel did not look at</p> <p>25 any case-control studies?</p>	<p style="text-align: right;">Page 116</p> <p>1 and those can have case-control studies in them.</p> <p>2 It's just that when they do their meta-analyses,</p> <p>3 which is actually looking at data from the various</p> <p>4 studies, they make the choice for nutrition variables to</p> <p>5 focus on cohort studies for some cancers and some</p> <p>6 exposures.</p> <p>7 As I mentioned, arsenic, there was some other</p> <p>8 exposures, like very hot teas that were studied in</p> <p>9 case-control studies, so that's not a complete sentence--</p> <p>10 statement for all of the projects.</p> <p>11 MR. WILLIAMS: I move to strike that</p> <p>12 as nonresponsive.</p> <p>13 Q (By Mr. Williams) My question to you is this:</p> <p>14 The last sentence under "Methodology" on Page 9 of</p> <p>15 this exhibit, Exhibit No. 5, says that "Due to their</p> <p>16 methodological limitations, case-control studies were not</p> <p>17 analyzed in the Ovarian Cancer SLR 2013."</p> <p>18 That's what it says, right?</p> <p>19 A And I was explaining what it means.</p> <p>20 Q You would agree with me that each study design, cohort</p> <p>21 study, case-control study, other types of studies, has</p> <p>22 its advantages and limitations, correct?</p> <p>23 A That's true.</p> <p>24 Q And you would agree that the hierarchy of epidemiological</p> <p>25 evidence places cohort studies above case-control</p>
<p style="text-align: right;">Page 115</p> <p>1 A That's not true for the entire work that we did.</p> <p>2 For some of the cancers and some of the exposures we</p> <p>3 did include case-control studies; for example, arsenic</p> <p>4 and some other carcinogens.</p> <p>5 When I mentioned that the Bradford Hill aspects were</p> <p>6 extended for this analysis, it is particularly because of</p> <p>7 nutrition variables.</p> <p>8 Nutrition variables are very difficult to ascertain</p> <p>9 for exposure because as opposed to the use of talcum</p> <p>10 powder products, which might be used once or twice a day,</p> <p>11 nutrition variables are occurring sometimes 50 to 100</p> <p>12 times a day.</p> <p>13 The amount that people eat, what they're eating, how</p> <p>14 often they're eating, the variables are so difficult to</p> <p>15 collect, that the results from case-control studies are a</p> <p>16 concern to some investigators.</p> <p>17 Many epidemiologists disagree with this choice of</p> <p>18 what World Cancer Research Fund decided to do.</p> <p>19 When it says-- however, I should also mention when</p> <p>20 it says, "analyzed," that's analyzed for the</p> <p>21 meta-analysis.</p> <p>22 The World Cancer Research Fund, when they do the</p> <p>23 systematic reviews, also looks for pooled analyses and</p> <p>24 meta-analyses, and they present them in the SLR, and</p> <p>25 reports will have information from those other reports,</p>	<p style="text-align: right;">Page 117</p> <p>1 studies?</p> <p>2 MS. PARFITT: Objection; form.</p> <p>3 THE WITNESS: I would say the</p> <p>4 hierarchy of epidemiology evidence depends entirely on</p> <p>5 the question under review.</p> <p>6 If you have an exposure, which is very difficult to</p> <p>7 measure and which can change over time or which you are</p> <p>8 trying to determine lifetime exposure, then often it's</p> <p>9 more-- it's easier to do that in a case-control study.</p> <p>10 The case-control studies that were reviewed for the</p> <p>11 talcum powder product used and ovarian cancer risk</p> <p>12 primarily used interview questionnaires, so an</p> <p>13 interviewer spending time, sometimes several hours with a</p> <p>14 patient in control, to determine lifetime exposures.</p> <p>15 The cohort studies, however, typically, and</p> <p>16 especially the three cohort studies that were included in</p> <p>17 this review and that have been published on ovarian</p> <p>18 cancer and talcum powder products, those studies were</p> <p>19 designed to look at multiple diseases.</p> <p>20 Nurses' Health Study was started to--</p> <p>21 Q (By Mr. Williams) Ma'am, I am going to have to cut you</p> <p>22 off because-- look, when I ask you questions, I need you</p> <p>23 to answer the question that I've asked. Otherwise, you</p> <p>24 could just talk for a half an hour, so if you would,</p> <p>25 please, Doctor, just focus on the question that I'm</p>

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<p style="text-align: right;">Page 118</p> <p>1 asking you.</p> <p>2 The question that I'm asking you is:</p> <p>3 As a matter of epidemiological practice in your line</p> <p>4 of work, is it true or not true that case-- excuse me,</p> <p>5 that cohort studies are placed higher in the hierarchy</p> <p>6 than case-control studies?</p> <p>7 If the answer is that's not true, please just say</p> <p>8 it's not true.</p> <p>9 MS. PARFITT: Objection to form; asked</p> <p>10 and answered.</p> <p>11 THE WITNESS: I think-- yeah, I did</p> <p>12 try to answer that before. I will try to do it better</p> <p>13 this time.</p> <p>14 For one thing, I am not sure what hierarchy you are</p> <p>15 referring to, but what I'm saying is that depending on</p> <p>16 the question, one type of study could be preferable to</p> <p>17 another, but in general all of the studies provide</p> <p>18 information, and we look at the totality of evidence.</p> <p>19 Q (By Mr. Williams) So it is your view that there is no</p> <p>20 generally accepted hierarchy of epidemiological evidence?</p> <p>21 MS. PARFITT: Objection; form,</p> <p>22 misstates her testimony.</p> <p>23 THE WITNESS: I think it depends</p> <p>24 entirely on what the question is.</p> <p>25 Q (By Mr. Williams) Let's look at Exhibit No. 10, which is</p>	<p style="text-align: right;">Page 120</p> <p>1 question to you now is:</p> <p>2 Is it your testimony that there is in fact no</p> <p>3 generally accepted hierarchy of epidemiological evidence</p> <p>4 that places cohort studies above case-control studies?</p> <p>5 MS. PARFITT: Objection.</p> <p>6 THE WITNESS: And I would again say it</p> <p>7 depends entirely on the question, the scientific</p> <p>8 question.</p> <p>9 Q (By Mr. Williams) Here this references that cohort</p> <p>10 studies are likely to be the main source of evidence</p> <p>11 owing to the long latent period for cancer and owing to</p> <p>12 their prospective design.</p> <p>13 Those are the two concepts that it mentions in that</p> <p>14 sentence, correct?</p> <p>15 A That's what that mentions, yes.</p> <p>16 Q And the latent period for cancer refers to the fact that</p> <p>17 exposure to a substance can sometimes take some time</p> <p>18 before cancer is developed, right?</p> <p>19 A That's correct.</p> <p>20 Q That's the latency period?</p> <p>21 A Yes.</p> <p>22 Q And the idea of a prospective cohort study is that people</p> <p>23 are asked about their-- what they do and put on and in</p> <p>24 their bodies right now when they are healthy, and then</p> <p>25 they are followed along, correct?</p>
<p style="text-align: right;">Page 119</p> <p>1 the "Judging the evidence" document from 2018 from the</p> <p>2 World Cancer Research Fund, and I will direct your</p> <p>3 attention to the seventh page.</p> <p>4 At the bottom of Page 7 of this exhibit, Exhibit</p> <p>5 No. 10, it has a section that says, "Study design," that</p> <p>6 says, "Each study design has its advantages and</p> <p>7 limitations. The hierarchy of epidemiological evidence</p> <p>8 places cohort studies above case-control studies, with</p> <p>9 ecological studies and case reports at the bottom.</p> <p>10 "There are merits in considering a number of</p> <p>11 different study designs. Cohort studies are likely to be</p> <p>12 the main source of evidence owing to the long latent</p> <p>13 period for cancer to develop and also to their</p> <p>14 prospective design"--</p> <p>15 A I'm sorry, can you say where you're reading from?</p> <p>16 MS. PARFITT: 7. He's right here.</p> <p>17 THE WITNESS: Okay.</p> <p>18 Q (By Mr. Williams) And I've read through that heading,</p> <p>19 "Study design," through to the last sentence that says,</p> <p>20 "However, in some circumstances case-control studies and</p> <p>21 ecological studies may also make a useful contribution to</p> <p>22 the evidence," and it refers to Section 7.</p> <p>23 Do you see that?</p> <p>24 A Yes.</p> <p>25 Q Now, we are going to go to Section 7 in a minute, but my</p>	<p style="text-align: right;">Page 121</p> <p>1 A That's correct.</p> <p>2 Q Okay. And retrospective case-control studies are</p> <p>3 backwards-looking where people are asked questions after</p> <p>4 they have contracted a disease and they are asked to</p> <p>5 recall what they put on and in their bodies, true?</p> <p>6 A So that is typical.</p> <p>7 Cohort studies, by the way, could also ask</p> <p>8 retrospectively what somebody had done over their</p> <p>9 lifetime.</p> <p>10 In this particular case, with talcum powder</p> <p>11 products, they did, but I have seen many studies do that.</p> <p>12 They can do a lifetime exposure, and then if-- the</p> <p>13 better cohort studies focused on certain-- depending on</p> <p>14 the question, they update their data so that then you</p> <p>15 could have a lifetime exposure variable from a cohort</p> <p>16 study.</p> <p>17 For the-- in terms of long latent period for cancer,</p> <p>18 case-control studies, if they're asking about lifetime</p> <p>19 exposure and collecting that information, that would not</p> <p>20 be an issue or a problem for case-control studies.</p> <p>21 Q Let me have you turn to Section No. 7, which is on Page</p> <p>22 21.</p> <p>23 That's the section that's referred to at the end of</p> <p>24 the page we were just looking at, the study design</p> <p>25 section referring to Section 7, so I want to go there.</p>

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<p style="text-align: right;">Page 122</p> <p>1 Do you have Page 21 in front of you?</p> <p>2 A Yeah.</p> <p>3 Q In the left-hand column under Section 7, "Evidence</p> <p>4 collated for the Continuous Update Project," at the very</p> <p>5 bottom, it has the sentence that says, "The first stage</p> <p>6 of the SLRs was a comprehensive search using a</p> <p>7 standardized search strategy for the scientific</p> <p>8 literature for randomized trials and cohort studies</p> <p>9 published since 2006 using Medline. Because case-control</p> <p>10 studies are particularly prone to recall (and other)</p> <p>11 bias, they were not routinely reviewed"--</p> <p>12 A Where are you again? Okay. Sorry.</p> <p>13 MS. PARFITT: Just give her a moment,</p> <p>14 Mr. Williams, to catch up.</p> <p>15 Q (By Mr. Williams) Do you see where I am?</p> <p>16 A Yes.</p> <p>17 Q In the right-hand column of Page 21 it says, "Because</p> <p>18 case-control studies are particularly prone to recall</p> <p>19 (and other) bias, they were not routinely reviewed.</p> <p>20 "However, if there were no or very few RCTs or</p> <p>21 cohort studies, they were included."</p> <p>22 Do you see that?</p> <p>23 A Yes.</p> <p>24 Q In the case of talc and ovarian cancer, as of 2018, is it</p> <p>25 accurate to say that there are five cohort studies that</p>	<p style="text-align: right;">Page 124</p> <p>1 showed that there was no statistically significant</p> <p>2 relationship between talc use and ovarian cancer,</p> <p>3 correct?</p> <p>4 MS. PARFITT: Objection; form.</p> <p>5 THE WITNESS: One of those studies did</p> <p>6 show a statistically significant association with use of</p> <p>7 talcum powder products and risk of serous ovarian cancer,</p> <p>8 and that was the Gertig study, but I also did an analysis</p> <p>9 showing there was insufficient number of cases in all</p> <p>10 three of those studies in order to find a statistically</p> <p>11 significant result.</p> <p>12 The driver of statistical significance is the number</p> <p>13 of cases in a study, regardless of whether it's a cohort</p> <p>14 study or case-control study.</p> <p>15 Q (By Mr. Williams) We will get to the number of cases in</p> <p>16 a moment, but with respect to the Gertig study, you are</p> <p>17 aware and came across in your review, because you</p> <p>18 referenced them in your report, that that Gertig study</p> <p>19 was updated in 2008 and 2010 under the name "Gates,"</p> <p>20 correct?</p> <p>21 MS. PARFITT: Objection; form.</p> <p>22 THE WITNESS: 2008 I would not call an</p> <p>23 update.</p> <p>24 It only included 200 cases from the Nurses' Health</p> <p>25 Study. It also included other cases from the New England</p>
<p style="text-align: right;">Page 123</p> <p>1 you have had the benefit of reviewing?</p> <p>2 A That is not correct.</p> <p>3 In the three cohort studies, one of which had three</p> <p>4 publications with different numbers of cases in them--</p> <p>5 there are three cohort studies.</p> <p>6 Q So if we count the study that has three different cohort</p> <p>7 studies within it, and then add the other two cohort</p> <p>8 studies, we would get to five; would we not?</p> <p>9 MS. PARFITT: Objection; form.</p> <p>10 THE WITNESS: I repeat, the three</p> <p>11 cohort studies, just that one of them has three</p> <p>12 publications.</p> <p>13 Q (By Mr. Williams) And do you consider three cohort</p> <p>14 studies, one of which had three separate sets of data, to</p> <p>15 be insufficient to do an analysis of whether talc causes</p> <p>16 ovarian cancer?</p> <p>17 MS. PARFITT: Objection; form.</p> <p>18 THE WITNESS: I would consider those</p> <p>19 three-- what I would do is look at the individual studies</p> <p>20 of those three studies. I would look at how the data</p> <p>21 were collected and whether you can get the information</p> <p>22 that you want to look at your question, before deciding</p> <p>23 that they were sufficient on their own.</p> <p>24 Q (By Mr. Williams) Every single cohort study that you</p> <p>25 looked at in this case, for your work in this litigation,</p>	<p style="text-align: right;">Page 125</p> <p>1 case-control study, so when you look at just the Nurses'</p> <p>2 Health Study, part of it was only 200 cases, and it is</p> <p>3 very difficult to determine which cases those were.</p> <p>4 The second update wasn't an update, but at that time</p> <p>5 they ended up looking at a different variable, a</p> <p>6 different comparison.</p> <p>7 The first study compared no use, never-users, to</p> <p>8 users of different categories.</p> <p>9 The second-- the third study compared-- combined</p> <p>10 never-users with use of less than once a week, so you</p> <p>11 have a very different comparison, so I think that was--</p> <p>12 that was concerning.</p> <p>13 It's not clear it's a real update-- the data aren't</p> <p>14 really there.</p> <p>15 That third study also didn't focus just on talc.</p> <p>16 Talc was just one of the variables in the study.</p> <p>17 Q (By Mr. Williams) To the extent that the 2010 study by</p> <p>18 Gates, that update-- first of all, the 2010 update wasn't</p> <p>19 an update.</p> <p>20 You just said that yourself, correct, Doctor?</p> <p>21 MS. PARFITT: Objection.</p> <p>22 THE WITNESS: It was an update of</p> <p>23 cases.</p> <p>24 It is not clear it was an update of the data.</p> <p>25 Q (By Mr. Williams) True or not true, the 2010 Gates</p>

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<p style="text-align: right;">Page 126</p> <p>1 update did not show a statistically significant increased 2 risk of serous invasive ovarian cancer? 3 MS. PARFITT: Objection. 4 THE WITNESS: It did not show a 5 statistically significant association, correct. 6 Q (By Mr. Williams) Can you identify any cohort study that 7 concluded that there was a statistically significant 8 overall association between talc and ovarian cancer? 9 MS. PARFITT: Objection; form. 10 THE WITNESS: So you are talking about 11 for talc and any type of epithelial ovarian cancer? 12 Q (By Mr. Williams) Any statistically significant overall 13 association between talc and ovarian cancer. 14 A That's correct, I didn't have sufficient sample size to 15 do it. 16 Q The answer to my question is that you cannot identify any 17 cohort study concluding that there was a statistically 18 significant overall association between talc and ovarian 19 cancer, correct? 20 MS. PARFITT: Objection to form; asked 21 and answered. 22 Q (By Mr. Williams) You may answer, Doctor. 23 A So my answer is the same, that statistical significance 24 is not seen because the sample size is too small. 25 Q Is there any other reason why statistical significance</p>	<p style="text-align: right;">Page 128</p> <p>1 12:30? What's your pleasure? 2 MS. PARFITT: Can we go off the 3 record? 4 MR. WILLIAMS: Let's go off the 5 record. 6 VIDEOGRAPHER: Going off record, the 7 time is 12:07 p.m. 8 (Recess 12:07 to 12:00 p.m.) 9 10 VIDEOGRAPHER: We are back on the 11 record. The time is 12:09 p.m. 12 Q (By Mr. Williams) Dr. McTiernan, would you agree that if 13 you had only looked at the cohort studies in this case, 14 like it is suggested is appropriate in the World Cancer 15 Research Fund "Judging the evidence" document, Exhibit 16 No. 10, that you would not have been able to opine that 17 talcum powder causes ovarian cancer? 18 MS. PARFITT: Objection; form. 19 THE WITNESS: First I want to respond 20 by characterizing the World Cancer Research Fund 21 document, that they're referring to nutrition variables, 22 so that is why they consider case-control studies to be a 23 much lower hierarchy than cohort studies. 24 In terms of what was seen in the cohort studies, we 25 did see, with the Nurses' Health Study, elevated risk of</p>
<p style="text-align: right;">Page 127</p> <p>1 was not seen besides the sample size being too small? 2 A Sample size is one of the major drivers. 3 The other thing is there is a lot of variability 4 around the point estimate, the relative risk. 5 When you see a sample size that's that small, that's 6 the major thing you start thinking about. 7 Q Other than sample size and variability, is there any 8 other factor that you believe makes the cohort studies 9 unreliable? 10 A I don't think I used the word "unreliable." I used the 11 word "not statistically significant." 12 MS. PARFITT: Objection. 13 Q (By Mr. Williams) Other than sample size and 14 variability, is there anything else that bears upon 15 statistical significance that is important? 16 MS. PARFITT: Objection; form. 17 You are referring to the collective group of cohort 18 studies? 19 THE WITNESS: The statistical 20 significance-- you are not talking about the effects. 21 You are talking about statistical significance. Those 22 are the things that would drive it, in my opinion. 23 MR. WILLIAMS: Counsel, I am going to 24 go to a different topic. 25 Do you want to take lunch now? Do you want to go</p>	<p style="text-align: right;">Page 129</p> <p>1 serous cancer. 2 We also saw in the two cohort studies elevated risk 3 that was not statistically significant, and I-- my 4 opinion is that's because the sample size was small. 5 In answer, two of the three cohort studies did show 6 elevated risk of ovarian cancer, but they were not 7 statistically significant, with the exception to the 8 serous subtype in the Nurses' Health Study. 9 Q (By Mr. Williams) Have you completed your answer? 10 A Yes. 11 Q The only type of cancer for which there was a 12 statistically significant finding in one of the studies 13 related to serous invasive ovarian cancer, correct? 14 A Only one type showing statistical significance around 15 that relative risk, yes. 16 Q And that was the Gertig 2000 study? 17 A Yes. 18 The-- 19 Q Ma'am, you have answered my question. 20 Was the Gertig 2000 study the only study where there 21 was a statistically significant finding that serous 22 invasive ovarian cancer was associated with talc use? 23 MS. PARFITT: Objection; form. 24 THE WITNESS: For the cohort studies, 25 yes, that's correct.</p>

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<p style="text-align: right;">Page 130</p> <p>1 Q (By Mr. Williams) I take it you and I disagree as to 2 whether or not the Gates 2010 update showed that that 3 previously seen statistically significant increased risk 4 for serous invasive cancer went away? 5 You think it did not go away. I represented to you 6 that the study says that it did go away, right? 7 MS. PARFITT: Objection; form. 8 THE WITNESS: My issue with them is 9 not-- is that different comparisons were made. 10 The first one looked at never-use versus ever-use-- 11 Q (By Mr. Williams) You have already explained that, 12 ma'am-- 13 MS. PARFITT: Please allow her to 14 complete. 15 THE WITNESS: I am just referring to 16 my answer. 17 The second study, the 2010 Gates study, was then 18 comparing never-user plus less than once a week use 19 versus greater use, so it's a different comparison. 20 That's going to dampen, going to lower the relative risk 21 by putting some of the users in with the nonusers. 22 Q (By Mr. Williams) The Gates 2010 study did not show a 23 statistically significant increased risk for serous 24 invasive ovarian cancer, true or not true? 25 MS. PARFITT: Objection; form, asked</p>	<p style="text-align: right;">Page 132</p> <p>1 World Cancer Research report or my report? 2 Q (By Mr. Williams) I am referring to-- 3 A For the talcum powder products-- 4 Q I'll restate the question. 5 For purposes of preparing your report, Exhibit No. 2 6 for this deposition, which is the report you prepared for 7 this litigation-- do you have that in mind? 8 A Yes. 9 Q It is true that you relied heavily on Exhibit No. 10, the 10 "Judging the evidence" document, in preparing your 11 report, which is Exhibit No. 2? 12 MS. PARFITT: Objection; form. 13 THE WITNESS: I didn't rely heavily. 14 I cited it as some of the methods of reviewing 15 meta-analyses. I used some of the methods that I used 16 for that as well as what was used for the government 17 physical activity guidelines, but I did not use this 18 entirely. 19 In terms of determining causality, I used-- I went 20 back to the original Bradford Hill aspects, listed 21 aspects, to determine causality. I did not use the 22 guidelines for the CUP analysis in determining whether 23 the association that's seen between talcum powder 24 products and risk of ovarian cancer meets criteria for 25 causal.</p>
<p style="text-align: right;">Page 131</p> <p>1 and answered. 2 THE WITNESS: It showed a six percent 3 increase in risk that was not statistically significant, 4 and it's not comparing nonusers to users. It's comparing 5 nonusers plus less-than-once-a-week users to more-often 6 users. 7 Q (By Mr. Williams) Let me ask you to look, Doctor, at 8 Exhibit No. 10-- 9 A Which one? 10 Q Exhibit No. 10, the "Judging the risk" document from 11 2018-- excuse me, "Judging the evidence." 12 I misspoke. 13 First, I haven't done this yet, but if you look at 14 Page 30, the acknowledgments section, it lists you as a 15 panel member for this review, correct? 16 A Yes. 17 Q It is true that you relied very heavily on this document, 18 that is Exhibit No. 10, in drafting your report for this 19 case? 20 MS. PARFITT: Objection; misstates 21 testimony. 22 THE WITNESS: I did not draft this 23 report. 24 Is that what you mean? 25 The World Cancer-- so you are talking about the</p>	<p style="text-align: right;">Page 133</p> <p>1 Q (By Mr. Williams) Let me be very specific about what I 2 mean. 3 When you were typing up Exhibit No. 2, your report 4 for this case, you literally had this exhibit, Exhibit 5 No. 10, next to you as you typed? 6 MS. PARFITT: Objection. 7 Q (By Mr. Williams) True or not true? 8 MS. PARFITT: Objection; form. 9 THE WITNESS: It's not true. 10 Q (By Mr. Williams) Is it your testimony that you prepared 11 your report without any reference at all to any part of 12 Exhibit No. 10? 13 A I did reference it. It's one of the references here. 14 Q Show me that, if you would. 15 A I think-- I used-- I included the website. 16 Q You included the website for the 2014 report on Page 5 of 17 your report, but if you did refer to this document, 18 Exhibit No. 10, in your references or anywhere else, 19 please let me know where that is. 20 A So I don't see it if I did. 21 Q Have you completed your answer? 22 A What was the question again? 23 Q I was asking you to point out for me-- 24 A Did I refer to it or did I reference it? 25 I may not have referenced it.</p>

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<p style="text-align: right;">Page 134</p> <p>1 I thought I had.</p> <p>2 Yeah, I just have the website here.</p> <p>3 Q Let me refer you to your report in this case, Exhibit</p> <p>4 No. 2, and ask you to turn to Page 10.</p> <p>5 You have a heading that says, "The science of</p> <p>6 epidemiology" at Page 10.</p> <p>7 Do you see that?</p> <p>8 A Yes.</p> <p>9 Q And with the first paragraph there, starting about a</p> <p>10 third of the way into the paragraph, you write,</p> <p>11 "Epidemiological research describes and seeks to explain</p> <p>12 the distribution of health and disease within human</p> <p>13 populations."</p> <p>14 Did I read that correctly?</p> <p>15 A Yes.</p> <p>16 Q And skipping a sentence, you write, "This type of</p> <p>17 investigation is known as observational. By relating</p> <p>18 differences in circumstances and behavior to differences</p> <p>19 in the incidence of disease, associations are identified</p> <p>20 that may or may not be causal."</p> <p>21 Is that what it says?</p> <p>22 A Yes.</p> <p>23 Q And then the first sentence of the next paragraph says,</p> <p>24 "In epidemiological studies, an exposure is a factor or</p> <p>25 condition that may or may not influence the risk of</p>	<p style="text-align: right;">Page 136</p> <p>1 Is it accurate to say that the sentences that are</p> <p>2 set forth under that heading, "Epidemiological evidence,"</p> <p>3 are identical to sentences found in your report on Page</p> <p>4 10, with one exception, that there is a sentence that</p> <p>5 appears in your report that does not appear on Page 6 of</p> <p>6 Exhibit No. 10?</p> <p>7 MS. PARFITT: Object to the form of</p> <p>8 the question.</p> <p>9 THE WITNESS: I think you are talking</p> <p>10 about the sentences up here.</p> <p>11 Q (By Mr. Williams) I am actually talking about the three</p> <p>12 sentences that I read from Page 10 of your report, two</p> <p>13 sentences from the first paragraph, and one sentence, the</p> <p>14 first sentence from the second paragraph.</p> <p>15 Those three sentences are identical, word for word,</p> <p>16 to the sentences that appear on Page 6 of Exhibit No. 10?</p> <p>17 MS. PARFITT: Objection; form.</p> <p>18 Q (By Mr. Williams) Correct?</p> <p>19 A Yes.</p> <p>20 Q Now, just so we're clear, did you provide the people who</p> <p>21 wrote the text of the World Cancer Research Fund a copy</p> <p>22 of your expert report in this case when this document,</p> <p>23 "Judging the evidence" was prepared?</p> <p>24 A No, they did not get a copy of this.</p> <p>25 Nobody has seen it, other than Ms. Parfitt and her</p>
<p style="text-align: right;">Page 135</p> <p>1 disease," right?</p> <p>2 A Yes.</p> <p>3 Q Throughout your report you included a lot of citations to</p> <p>4 works that you relied upon, correct?</p> <p>5 A Yes.</p> <p>6 Q Your reference section includes, I think we said, 127</p> <p>7 citations, right?</p> <p>8 A Yes.</p> <p>9 Q You did not provide a citation for any of the sentences</p> <p>10 that we just read, right?</p> <p>11 A That is not here, no.</p> <p>12 Q And by that I mean there is no reference to a footnote,</p> <p>13 there is no reference to any of the 127 items in the back</p> <p>14 of your report, correct?</p> <p>15 A That's correct.</p> <p>16 Q Now, turn back to the "Judging the evidence" document,</p> <p>17 which we marked as Exhibit No. 10, and I will ask you to</p> <p>18 turn to Page 6 under the heading, "Epidemiological</p> <p>19 evidence."</p> <p>20 Right underneath that heading the "Judging the</p> <p>21 evidence" document from the World Cancer Research Fund</p> <p>22 says, and I'm quoting, "Epidemiological research</p> <p>23 describes and seeks to explain the distribution of health</p> <p>24 and disease within human populations," and I will stop</p> <p>25 there.</p>	<p style="text-align: right;">Page 137</p> <p>1 colleagues.</p> <p>2 Q So to this day there is nobody from the WCRF who has seen</p> <p>3 your expert report in this litigation, correct?</p> <p>4 A That's correct.</p> <p>5 Q So the way this work was, you had in front of you Exhibit</p> <p>6 No. 10, and you prepared-- took out sentences from the</p> <p>7 WCRF document and included them word for word in your</p> <p>8 report, correct?</p> <p>9 MS. PARFITT: Objection; form.</p> <p>10 THE WITNESS: I can't recall where I</p> <p>11 took this.</p> <p>12 I have many different documents where I have</p> <p>13 information about what epidemiology is.</p> <p>14 If I took it from here, I should have cited it, but</p> <p>15 I can't recall where exact sentences came from.</p> <p>16 Q (By Mr. Williams) Wherever you took it from--</p> <p>17 A I should have cited it.</p> <p>18 Q Whether it was the "Judging the evidence" document or</p> <p>19 someplace else, you didn't cite it?</p> <p>20 A I should have cited it, you're right.</p> <p>21 Q Now, we went through your expert report and the</p> <p>22 Continuous Update Project's "Judging the evidence"</p> <p>23 document, Exhibit No. 10, and we put the text side by</p> <p>24 side for various sections for ease of reference, and I'm</p> <p>25 going to pass those out to you, and we'll mark it as</p>

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<p style="text-align: right;">Page 138</p> <p>1 Exhibit No. 11. 2 We will give it to Counsel. 3 (Exhibit No. 11 marked 4 for identification.) 5 6 Q (By Mr. Williams) Now, what we set forth here are a 7 total of 13 different places where the language from the 8 "Judging the evidence" report was used word for word, 9 with some exceptions, in your report. 10 Do you see that? 11 I am not asking you to agree or disagree, but let me 12 ask you to see that there are 13 different examples where 13 the language is either word for word or roughly word for 14 word used in your report, taking language that also 15 appears in the "Judging the evidence" report. 16 Do you see that? 17 Take your time to look through there. 18 MS. PARFITT: Objection to form. 19 THE WITNESS: I can see that some of 20 these are very common epidemiologic terms. 21 Q (By Mr. Williams) Let's look for a little-- why don't 22 you put that to one side for a moment and let me just ask 23 you some other questions, and then we'll take lunch. 24 I want to discuss a few places where it appears that 25 you copied from the "Judging the evidence" document and</p>	<p style="text-align: right;">Page 140</p> <p>1 "The combination of data from multiple studies 2 creates a larger data set and increased statistical 3 power." 4 Did I read that right from Exhibit No. 10? 5 A Yes. 6 Q Now, when you prepared your litigation report, you copied 7 a lot of the language verbatim into your litigation 8 report but made a few changes. 9 Have you noticed those? 10 MS. PARFITT: Objection to that form. 11 Q (By Mr. Williams) Let me refer you to Exhibit No. 2, 12 Page 22 of your report. 13 Exhibit No. 2, Page 22. 14 I would ask you to keep Exhibit No. 2, Page 22 open 15 and keep Page 11 of Exhibit No. 10 open, and put them 16 side by side. 17 Referring you now to Page 22 of Exhibit No. 2, the 18 first full paragraph on that page says, "Pooled analysis 19 is a type of meta-analysis where original 20 individual-level data from various published and/or 21 unpublished epidemiological studies are combined and 22 re-analyzed." 23 Did I read that correctly from your report? 24 A Yes. 25 Q Now, when you wrote your report, the only difference</p>
<p style="text-align: right;">Page 139</p> <p>1 made some changes. 2 MS. PARFITT: And I will object to the 3 form of that. 4 Please continue. 5 Q (By Mr. Williams) In describing what a pooled analysis 6 is in the Continuous Update Project report, and I will 7 refer you to Exhibit No. 10 at Page 11, in the right-hand 8 column-- 9 MS. PARFITT: Just give us a moment-- 10 THE WITNESS: Exhibit No. 10? 11 Q (By Mr. Williams) Right, Exhibit No. 10 at Page 11 on 12 the right-hand column. 13 There is a heading that says-- there's a paragraph 14 that begins, "Pooled analysis," last paragraph on the 15 page. 16 Do you see that? 17 A Mm-hm. 18 Q Is that a "yes"? 19 A Yes. 20 Q In Exhibit No. 10, which is the "Judging the evidence" 21 document, it says, "Pooled analysis is a type of 22 meta-analysis in which original individual-level data 23 from various published epidemiological studies of a 24 similar type - usually prospective cohort studies - are 25 combined and re-analyzed.</p>	<p style="text-align: right;">Page 141</p> <p>1 between the language that's set forth in Exhibit No. 10, 2 in that first sentence, the only language that is added 3 is "and/or unpublished." 4 Do you see that? 5 A Yes. 6 Q So while the Exhibit No. 10, the "Judging the evidence" 7 document that was put out by the World Cancer Research 8 Fund, when they described a pooled analysis, they didn't 9 say anything about unpublished studies, true? 10 A So again-- 11 Q Pardon me? 12 I am asking you to look at Exhibit No. 10, Page 11. 13 A Right. 14 Q Right-hand column. 15 A Right. 16 Q That sentence does not say anything about "and/or 17 unpublished," does it? 18 A Right-- yes, it doesn't. 19 Q And then in that sentence, if you go back to Page 22 of 20 your report, after you added "and/or unpublished 21 epidemiological studies," you took out some information, 22 did you not, some words? 23 A What are you referring to that I took out? 24 Q Well, the words that you took out were, dash, "Usually 25 prospective cohort studies," dash, right?</p>

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<p style="text-align: right;">Page 142</p> <p>1 Actually, you also took out the words "of a similar 2 type," so let me restate the question. 3 In your report you took out the words "of a similar 4 type - usually prospective cohort studies"-- and I will 5 put a closed quote there. 6 You took those words out, right? 7 A So, again, I can't remember every place-- because when I 8 write projects, I do take sections from things that I've 9 previously been involved with, since I'm considered on 10 this panel and it's considered as something I'm involved 11 with. I should have cited it, but I would be citing 12 something that I'm part of. 13 This-- it's not true that pooled analyses is only 14 prospective cohort studies, and it is not even true that 15 it's usually. 16 Many pooled analyses of case-control studies-- there 17 are many pulled analyses of clinical trials, so when 18 they're saying, "usually prospective cohort studies," 19 they're referring for what they usually-- for their data 20 or WCRF data, are usually prospective for the nutrition 21 variables, so that's what they specified there. 22 Q The words "of a similar type - usually prospective cohort 23 studies," do not appear in your report. 24 Can we agree on that? 25 MS. PARFITT: Objection; form.</p>	<p style="text-align: right;">Page 144</p> <p>1 studies, but you changed that language for your 2 litigation report to include "unpublished studies," 3 right? 4 MS. PARFITT: Objection; form. 5 THE WITNESS: The Continuous Update 6 Project did make a decision to use only published data 7 because it did not have the personal power to get 8 unpublished. 9 It is typical in pooled analysis and sometimes in 10 meta-analyses to look for additional data if it's known 11 to exist, even if it's not published. 12 This is true for clinical trial pooled analyses, 13 case-control pooled analyses, and cohort pulled analyses. 14 It is not surprising at all that-- it was not 15 unusual to see that in the Terry pooled analysis there 16 were three studies that were previously unpublished that 17 were added to the published data for that pooled 18 analysis. 19 I've seen this for one of the pooled analyses we 20 relied on for the physical activity guidelines committee, 21 and so it's a common method. 22 As long as you use the same criteria to determine if 23 that study has valid data, then it's quite customary to 24 include it in a pooled analysis. 25 Q (By Mr. Williams) The only pooled analysis that you</p>
<p style="text-align: right;">Page 143</p> <p>1 THE WITNESS: It wouldn't be relevant 2 because I am talking generally about pooled analysis, and 3 it's individual data from-- it could be any type of 4 studies. 5 I mentioned it could be clinical trials. There are 6 many pooled analyses of clinical trials. 7 It could be cohort studies, it could be case-control 8 studies. 9 And sometimes the cohorts and case-control studies 10 will be combined together where the cohort studies are 11 nested case-control studies, so it could be a combination 12 of two different types. 13 MR. WILLIAMS: I move to strike that 14 as nonresponsive. 15 Q (By Mr. Williams) Doctor, my question is this: 16 The words "of a similar type - usually prospective 17 cohort studies," those words do not appear in your 18 report. 19 Can we agree on that? 20 MS. PARFITT: Objection; form, asked 21 and answered. 22 THE WITNESS: I agree they don't 23 appear in my report. 24 Q (By Mr. Williams) So the Continuous Update Project 25 document stated that you should only pool published</p>	<p style="text-align: right;">Page 145</p> <p>1 looked at for this litigation was Terry 2013, correct? 2 MS. PARFITT: Objection; form. 3 THE WITNESS: It's the only one that 4 characterizes a pooled analysis. 5 There were some of the case-control studies that 6 added together more than one study. 7 The second study of the Nurses' Health Study was a 8 pooled analysis of Nurses' Health cases and New England 9 case-control studies, so that was a pooled study that 10 involved just two sets of studies. 11 Q (By Mr. Williams) The only pooled analysis that you 12 cited in your paragraph on Page 22, referencing Item 39, 13 which I'll represent to you is the Terry 2013 study, the 14 only pooled analysis that you studied in your report on 15 Page 22 is the Terry study, correct? 16 A I cited that singly because it was large enough. 17 My point is that it's large enough to be able to 18 look at some of these associations. 19 Q And that Terry 2013 study pooled eight case-control 20 studies, correct? 21 A That's correct. 22 It's a pooling project that has been done for many 23 other variables as well. 24 Q Doctor, we will be here all day and it will go late into 25 the night.</p>

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<p>1 I would ask you to answer just the question that I</p> <p>2 ask.</p> <p>3 The question that I'm asking you now is:</p> <p>4 The Terry 2013 pooled eight case-control studies,</p> <p>5 correct?</p> <p>6 That's all I'm asking.</p> <p>7 A That's correct.</p> <p>8 Q You deviated from the Continuous Update Project's</p> <p>9 definition of a pooled analysis, which is on Page 11 of</p> <p>10 Exhibit No. 10, in order to accommodate a study that you</p> <p>11 found helpful for the plaintiffs in this case, correct?</p> <p>12 MS. PARFITT: Objection; form,</p> <p>13 completely misstates her testimony and her opinions.</p> <p>14 You may answer.</p> <p>15 THE WITNESS: The Continuous Update</p> <p>16 Project definition was discussing studies related to</p> <p>17 nutrition, and the Continuous Update Project decided to</p> <p>18 only look at cohort studies for some of the relationships</p> <p>19 they were addressing.</p> <p>20 I believe this is why this sentence was written in</p> <p>21 that way, but it is not true that pooled analyses are</p> <p>22 usually prospective cohorts.</p> <p>23 If you look at pooled analyses in general, many of</p> <p>24 them are clinical trials, they are done in the treatment</p> <p>25 area, many of them are case-control studies, and many can</p>	<p>1 A That's correct.</p> <p>2 Q My question to you then is:</p> <p>3 Can you point us to any reference material anywhere</p> <p>4 that uses word for word the formulation for pooled</p> <p>5 analyses that you have set forth in the first two</p> <p>6 sentences of that paragraph?</p> <p>7 A So I think you're asking about pooled analyses that</p> <p>8 include studies that are not published; is that correct?</p> <p>9 Q I am asking the question that I asked.</p> <p>10 I will restate it one more time.</p> <p>11 Can you point us--</p> <p>12 MR. WILLIAMS: Counsel, I would as</p> <p>13 that you not point to anything.</p> <p>14 MS. PARFITT: I am just trying-- there</p> <p>15 is a monitor, for the Ladies and Gentlemen of the Jury,</p> <p>16 in front of the doctor, and I am just reminding her to</p> <p>17 look at the monitor, but you can--</p> <p>18 MR. WILLIAMS: I think that's</p> <p>19 inappropriate.</p> <p>20 Q (By Mr. Williams) But, Doctor, here is my question</p> <p>21 again:</p> <p>22 The first full paragraph on Page 22 describes pooled</p> <p>23 analyses. I'm referring you to the first two sentences</p> <p>24 there-- are you with me so far?</p> <p>25 A Yes.</p>
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<p>1 be cohort studies.</p> <p>2 Q (By Mr. Williams) Let me ask my question this way:</p> <p>3 Doctor, could you point us to some learned treatise,</p> <p>4 study, summary of studies that uses the formulation for</p> <p>5 pooled analysis word for word that is set forth on Page</p> <p>6 22 of your report; that is, could you point us to some</p> <p>7 source that says that pooled analyses is a type of</p> <p>8 meta-analysis that includes published and unpublished</p> <p>9 studies and that simultaneously does not reference</p> <p>10 prospective cohort studies?</p> <p>11 Is there something that you can point us to that</p> <p>12 uses the formulation for pooled analysis that you've set</p> <p>13 forth?</p> <p>14 MS. PARFITT: Objection; form.</p> <p>15 THE WITNESS: I'm a little bit</p> <p>16 confused by the question, but--</p> <p>17 Q (By Mr. Williams) Let me stop you there because if</p> <p>18 you're confused, it does me no good.</p> <p>19 I will restate it.</p> <p>20 Your paragraph here on Page 22 has one, and only</p> <p>21 one, citation, and that's to 39, the Terry 2013 study,</p> <p>22 correct?</p> <p>23 A That's correct.</p> <p>24 Q There are no other citations of any sort in that</p> <p>25 paragraph, correct?</p>	<p>1 Q Looking at those sentences word for word, and I mean</p> <p>2 every word in both of those two sentences-- are you still</p> <p>3 with me?</p> <p>4 A Yes.</p> <p>5 Q Okay. Looking at those two sentences, can you point us</p> <p>6 to any reference material that you have reviewed anywhere</p> <p>7 that describes pooled analyses using the words, and I</p> <p>8 mean word for word, as you set it forth here in the first</p> <p>9 two sentences of Paragraph No. 22?</p> <p>10 MS. PARFITT: Objection; form.</p> <p>11 Q (By Mr. Williams) You either can or you can't.</p> <p>12 The answer is yes, the answer is no.</p> <p>13 I just need to know--</p> <p>14 A Since I wrote that sentence, I am not sure where else it</p> <p>15 would be.</p> <p>16 If I was going to cite-- no, I can't.</p> <p>17 I wrote that sentence.</p> <p>18 Q Okay. What we do know is that the description of pooled</p> <p>19 analysis in Exhibit No. 10, which is the World Cancer</p> <p>20 Research Fund "Judging the evidence" document that has,</p> <p>21 on Page 2, a description of how one is to cite to it,</p> <p>22 what we do know is that that document describes pooled</p> <p>23 analysis as including published epidemiological studies</p> <p>24 of a similar type, usually prospective cohort studies,</p> <p>25 right?</p>

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<p>1 MS. PARFITT: Objection; form.</p> <p>2 THE WITNESS: And I disagree with that</p> <p>3 characterization of pooled studies.</p> <p>4 MR. WILLIAMS: Why don't we take a</p> <p>5 lunch break.</p> <p>6 VIDEOGRAPHER: Going off the record.</p> <p>7 The time is 12:40 p.m.</p> <p>8 (Lunch recess 12:40 to 1:21 p.m.)</p> <p>9</p> <p>10 VIDEOGRAPHER: We are going on the</p> <p>11 record at 1:21 p.m.</p> <p>12 This is the start of Media Unit 3.</p> <p>13 Q (By Mr. Williams) Good afternoon, Doctor.</p> <p>14 This morning there have been several occasions when</p> <p>15 I've used the word "ma'am," and I really apologize, and I</p> <p>16 mean no disrespect. I am going to try to use the word</p> <p>17 "Doctor."</p> <p>18 It's just how I was raised, and I apologize, but I</p> <p>19 do understand that that can be disrespectful. I don't</p> <p>20 mean that at all.</p> <p>21 A No problem. Thanks.</p> <p>22 Q In response to several of my questions earlier today</p> <p>23 about the various World Cancer Research Fund and CUP</p> <p>24 reports that we have marked as Exhibits 4, 5, and 10,</p> <p>25 there have been several times when you have made</p>	<p>1 A That's correct.</p> <p>2 Q Now, early menarche or age of first-- a woman first</p> <p>3 having her period is also listed as something that may be</p> <p>4 seen as a cause of ovarian cancer in this paragraph,</p> <p>5 right?</p> <p>6 A Yes.</p> <p>7 Q Can we agree that early menarche, not bearing children,</p> <p>8 and late natural menopause are not related to nutrition,</p> <p>9 physical activity, or diet?</p> <p>10 A This paragraph is related to background, and it's talking</p> <p>11 about menstrual cycles during a woman's lifetime. That's</p> <p>12 why it's talking about all of those variables related to</p> <p>13 early menarche, late menopause.</p> <p>14 I am not sure why whoever wrote this focused in on</p> <p>15 that, on a woman's menstrual cycle.</p> <p>16 They did not do a full systematic review of the risk</p> <p>17 factors for ovarian cancer.</p> <p>18 I can see from what was written here--</p> <p>19 Q Whether you consider it to be a full systematic review or</p> <p>20 not, my question is:</p> <p>21 Early menarche, not bearing children, and late</p> <p>22 natural menopause are not, in and of themselves, related</p> <p>23 to nutrition, physical activity, or diet, right?</p> <p>24 A And the whole report was not-- was to discuss and</p> <p>25 interpret and summarize meta-analyses-- for all of the</p>
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<p>1 reference to your view that the focus of those reports</p> <p>2 was on nutrition, physical activity, and diet.</p> <p>3 Do you recall that that has happened occasionally?</p> <p>4 A Yes.</p> <p>5 Q If you could take out Exhibit No. 5, which is the 2018</p> <p>6 report of the WCRF-- and I will ask you to turn to Page</p> <p>7 8.</p> <p>8 Section 4, "Other established causes," Page 8-- do</p> <p>9 you have that in front of you, ma'am?</p> <p>10 A Yes.</p> <p>11 Q Section No. 4 is entitled, "Other established causes,"</p> <p>12 and let me-- while you have that in front of you, let me</p> <p>13 ask:</p> <p>14 Not bearing children is listed as something that</p> <p>15 this report says may be a cause of ovarian cancer,</p> <p>16 correct?</p> <p>17 A It says, "May be seen as protective against ovarian</p> <p>18 cancer," yes.</p> <p>19 Q Well, actually, it says-- I will just read it. The</p> <p>20 second sentence says, "Not bearing children increases the</p> <p>21 risk of and may be seen as a cause of ovarian cancer,"</p> <p>22 and it goes on to say, "The reverse also applies: Bearing</p> <p>23 children reduces the risk of and may be seen as</p> <p>24 protective against ovarian cancer."</p> <p>25 Do you see that?</p>	<p>1 cancers, different writers put in paragraphs about some</p> <p>2 general factors about the cancers, and there was no</p> <p>3 effort to do a systematic review, so these are not causal</p> <p>4 analyses that were listed here.</p> <p>5 I don't know why these particular ones were picked.</p> <p>6 They're missing some.</p> <p>7 They're missing endometriosis, for example, as well</p> <p>8 as talcum powder.</p> <p>9 They are missing public inflammatory disease, so it</p> <p>10 is not a full review.</p> <p>11 For some reason they picked just some</p> <p>12 menstrual-related variables to mention here.</p> <p>13 Q Now, again, you said, "they."</p> <p>14 Once this draft was prepared, you have testified</p> <p>15 this morning that the panel, on which you are a member,</p> <p>16 reviews and makes judgments based upon the draft that is</p> <p>17 received, right?</p> <p>18 A In-- the 2014 draft.</p> <p>19 To my knowledge it was not changed.</p> <p>20 We did not see another update to review prior to the</p> <p>21 2018 publication of everything together.</p> <p>22 This was a 2014 document and it was on the website</p> <p>23 in 2014.</p> <p>24 Q I want the record to be clear the document that I'm</p> <p>25 referring you to right now, the Exhibit No. 5 to your</p>

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<p style="text-align: right;">Page 154</p> <p>1 deposition, is the revised document dated 2018.</p> <p>2 We have that clear, right?</p> <p>3 A Yes, but it also says, "2014" on the label for ovarian</p> <p>4 cancer.</p> <p>5 Q It does, but it also says that it was revised and</p> <p>6 published in 2018, right?</p> <p>7 I don't want to argue with you, but it does say that</p> <p>8 was revised and published in 2018, true?</p> <p>9 MS. PARFITT: Objection; form.</p> <p>10 Q (By Mr. Williams) Go ahead.</p> <p>11 A To my knowledge, the content was not changed.</p> <p>12 I am not sure exactly why it was called "Revised,"</p> <p>13 except that everything was put together and the</p> <p>14 recommendations were added to this obviously, the overall</p> <p>15 cancer recommendations, but to my knowledge the</p> <p>16 meta-analysis for the nutrition variables and all were</p> <p>17 not updated.</p> <p>18 Clearly this review of other potential causes was</p> <p>19 not updated, so in my mind it's the 2014 report.</p> <p>20 Q Now, let me focus you back on the lack of connection</p> <p>21 between early menarche, nutrition, and physical activity,</p> <p>22 and diet, okay?</p> <p>23 Whether you believe this was a complete analysis or</p> <p>24 not, the fact is that this report, which is marked as</p> <p>25 Exhibit No. 5, does discuss menarche, not bearing</p>	<p style="text-align: right;">Page 156</p> <p>1 talc or not using talc is a modifiable behavior.</p> <p>2 If you would, with your answer, as you describe how</p> <p>3 you think these are unrelated and different contexts, how</p> <p>4 is it that those contexts are different for purposes of</p> <p>5 the analysis that you have done in this case?</p> <p>6 MS. PARFITT: Objection; form.</p> <p>7 THE WITNESS: So this is an issue</p> <p>8 about measuring the exposure.</p> <p>9 If you ask about talcum powder product use, you</p> <p>10 typically are asking about something that is used once or</p> <p>11 twice a day.</p> <p>12 Somebody may just use one product. Perhaps they use</p> <p>13 more, but they're not going to be using as many variables</p> <p>14 as in nutrition.</p> <p>15 Assessing nutrition is extremely difficult.</p> <p>16 Assessing nutrition for a lifetime is even more</p> <p>17 difficult, and so this is why for case-control studies</p> <p>18 nutrition analyses are very difficult to do if you are</p> <p>19 trying to ask somebody retrospectively, "What did you eat</p> <p>20 when you were in your 20s?"</p> <p>21 You can ask somebody whether they used some products</p> <p>22 in their 20s and expect their recall to be much better</p> <p>23 than what they ate 30, 40 years ago because we are always</p> <p>24 talking about decades of latency between exposure and</p> <p>25 development of ovarian cancer.</p>
<p style="text-align: right;">Page 155</p> <p>1 children, and late menopause, right?</p> <p>2 MS. PARFITT: Objection; form.</p> <p>3 THE WITNESS: It does include those,</p> <p>4 and it's missing other risk factors for ovarian cancer.</p> <p>5 Q (By Mr. Williams) So the statement "Epidemiological</p> <p>6 principles" in this report, and those that we looked at</p> <p>7 in other exhibits, Exhibit 4 and Exhibit No. 10, do apply</p> <p>8 to your analysis of talc and ovarian cancer in this case,</p> <p>9 right?</p> <p>10 They do apply to things that are not limited to</p> <p>11 nutrition, physical activity, and diet, correct?</p> <p>12 MS. PARFITT: Objection; form,</p> <p>13 misstates her testimony.</p> <p>14 THE WITNESS: I am curious, what is</p> <p>15 the statement "epidemiologic principles"? Are you</p> <p>16 referring to something in this ovarian cancer report?</p> <p>17 Q (By Mr. Williams) Let me ask it this way:</p> <p>18 Why is it that nutrition is a totally separate</p> <p>19 context than talc?</p> <p>20 Explain, if you would, to the Court, who is the</p> <p>21 person who is going to review this-- describe to the</p> <p>22 Court how nutrition is a separate context than talc, with</p> <p>23 particular attention, Dr. McTiernan, to the notion that</p> <p>24 nutrition, what someone eats and takes into their body,</p> <p>25 is a modifiable behavior in the same manner that using</p>	<p style="text-align: right;">Page 157</p> <p>1 Case-control studies can be done for numbers of</p> <p>2 exposures, and they can be-- characterize exposure very</p> <p>3 well, but nutrition is a special case.</p> <p>4 Some epidemiologists still do do case-control</p> <p>5 studies of nutrition, but some, like-- because there are</p> <p>6 so many cohort studies available in nutrition, some</p> <p>7 epidemiologists prefer to look at that, especially when</p> <p>8 you're looking at a cancer that has a long latency</p> <p>9 period, and so you are looking for long interval between</p> <p>10 when the exposure happened and when the cancer occurred.</p> <p>11 Q (By Mr. Williams) Have you completed your answer?</p> <p>12 A Pardon me?</p> <p>13 Q Have you completed your answer?</p> <p>14 A Yes.</p> <p>15 Q Anything else that you want to add about the differences</p> <p>16 between the context of nutritional and dietary concerns</p> <p>17 versus the use of talcum powder?</p> <p>18 A I think that's it.</p> <p>19 Q Okay. Why is it harder to remember-- strike that.</p> <p>20 Why would it be harder for me or anyone else to</p> <p>21 remember the types of foods I ate in my teens or my 20s</p> <p>22 as compared to whether I used talcum powder during a</p> <p>23 particular time in my life?</p> <p>24 A When you ask people about nutrition, you don't just ask</p> <p>25 one question, "How often did you eat beef?"</p>

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<p style="text-align: right;">Page 158</p> <p>1 You are asking them for multiple types of foods, how 2 often they ate it, how much they ate it. 3 We often use food frequency questionnaires that can 4 be 12 pages long, each with about 20 to 30 items on them, 5 and to ask about-- somebody to recall that much 6 information retrospectively is more difficult than to ask 7 them to recall using one item. 8 Medications, we can often get information 9 retrospectively, like hormone therapy. We can ask that 10 about that case-control studies and help the woman 11 remember, but because it was one pill that the woman had 12 to take per day, it is an easier thing to remember than 13 50 to 100 variables that you have to remember with a 14 dietary recall. 15 Q Do you think it would be easier for a woman to recall 16 that she used talcum powder during her 20s than it would 17 be for her to recall that she ate red meat in her 20s? 18 A I think it would be easier in the sense that people are 19 going to remember something that intimate, how often-- 20 whether they used it or not, and we don't ask people just 21 one question, "Did you eat red meat?" 22 We ask them hundreds of questions of what they ate. 23 Q Do you ask hundreds of questions about red meat? 24 A We don't usually do studies with just red meat. 25 We do studies where we are asking about entire</p>	<p style="text-align: right;">Page 160</p> <p>1 THE WITNESS: I think if you wanted to 2 see if-- if you had just that one question, what somebody 3 ate, what meat they ate, a case-control study would be 4 just fine, you could ask somebody what they ate in the 5 past if it's just one variable. 6 If you're asking them to remember 50 to 100 7 variables, it's much more difficult. 8 Q (By Mr. Williams) Have we exhausted all of the reasons 9 why you believe that the context of this Exhibit No. 5, 10 this CUP update, is totally different, as you said, than 11 the context of the talc-related studies? 12 Is there anything else that you need to add to your 13 answer? 14 A I can't think of anything. 15 Q Pardon me? 16 A I can't think of anything, no. 17 Q Let me change topics slightly. 18 As an epidemiologist, you are familiar with a type 19 of bias called confounding, right? 20 A Yes. 21 Q Confounding is a type of bias that occurs when a third 22 variable interferes with a true relationship between an 23 exposure and an outcome, right? 24 A Yes. 25 Q Those are the words you used in your report, right?</p>
<p style="text-align: right;">Page 159</p> <p>1 dietary pattern. 2 I don't know of any study that asks just that one 3 question. 4 Q These studies that relate to talcum powder refer often to 5 multiple products and substances that a person puts on or 6 in her body; do they not? 7 MS. PARFITT: Objection; form. 8 THE WITNESS: From the questionnaires 9 that I've looked at from these studies, when they're 10 available, they are much simpler questions, and often 11 they were assisted with remembering by in-person 12 interview or telephone interview with someone that is 13 helping them remember what they did during that period of 14 life. 15 That can be used for a simple question, simple 16 exposure. 17 For diet, it's much more difficult. 18 Q (By Mr. Williams) I understand that some questionnaires 19 may be longer than others, but with respect to an 20 individual question, that is whether someone ate red meat 21 in their 20s or someone used talcum powder in their 20s, 22 do you really see those questions as-- one of those 23 questions as more complicated than the other, taken 24 individually? 25 MS. PARFITT: Objection to the form.</p>	<p style="text-align: right;">Page 161</p> <p>1 A Mm-hm. 2 Q "Yes"? 3 A Yes. 4 Q A confounder is one that is related both to the risk 5 disease and to the exposure, correct? 6 A That's correct. 7 Q The classic example that you use in your report is people 8 who carry matches are more likely to develop lung cancer 9 than individuals who do not carry matches, right? 10 A Correct. 11 Q In that example, the cause and effect relationship, the 12 true one, is not between matches and lung cancer, but 13 rather between smoking and lung cancer, correct? 14 A Correct. 15 Q Correlation does not equal causation, correct? 16 The two do not equate? 17 A I wouldn't go from one to the other, so-- this just means 18 that there's another variable explaining an association 19 in the first example, which is confounding. 20 Q Do you believe that correlation and causation mean one in 21 the same thing when you are dealing with epidemiological 22 studies? 23 A I don't usually use the word "correlation." 24 Association is one thing we look at when we're 25 trying to determine if there's a causal relationship.</p>

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<p style="text-align: right;">Page 162</p> <p>1 Q What I'm juxtaposing is correlation on the one hand and</p> <p>2 causation on the other.</p> <p>3 Do you have my question in mind?</p> <p>4 A I see it here, yes.</p> <p>5 Q Do you believe that correlation is identical to</p> <p>6 causation?</p> <p>7 MS. PARFITT: Objection; asked and</p> <p>8 answered.</p> <p>9 THE WITNESS: I think by "correlation"</p> <p>10 you mean "association."</p> <p>11 Q (By Mr. Williams) I mean a correlation between two</p> <p>12 variables.</p> <p>13 MS. PARFITT: Objection; form.</p> <p>14 THE WITNESS: Yeah, I think</p> <p>15 correlation is one way that two variables can be related,</p> <p>16 and causation is a much more complicated analysis.</p> <p>17 Q (By Mr. Williams) Same question with respect to</p> <p>18 association.</p> <p>19 Does association equate with causation?</p> <p>20 A I would say the same thing, association is part of causal</p> <p>21 analysis.</p> <p>22 Q So in a paper studying the association between</p> <p>23 match-carrying, for example, and lung cancer, you would</p> <p>24 need to adjust for smoking before making any conclusions</p> <p>25 about the risk estimates, true?</p>	<p style="text-align: right;">Page 164</p> <p>1 that Counsel gave you and produced to us on January 25th,</p> <p>2 a few days ago.</p> <p>3 Do you see that on the list?</p> <p>4 A No.</p> <p>5 Which list is this?</p> <p>6 MS. PARFITT: If I may, Counsel, I</p> <p>7 will hand her Exhibit No. 3.</p> <p>8 THE WITNESS: Oh, Kesmodel?</p> <p>9 MR. WILLIAMS: Yes.</p> <p>10 THE WITNESS: Yes.</p> <p>11 Q (By Mr. Williams) So Kesmodel is one of the studies that</p> <p>12 was provided to us, Defense counsel, by Plaintiffs'</p> <p>13 counsel on January 25th, correct?</p> <p>14 A Is that the date?</p> <p>15 Q That's the date we received it. I will represent that to</p> <p>16 you.</p> <p>17 A Okay.</p> <p>18 Q Have you read that study?</p> <p>19 A Yes.</p> <p>20 Q We'll mark that as Exhibit No. 12.</p> <p>21 (Exhibit No. 12 marked</p> <p>22 for identification.)</p> <p>23 ////</p> <p>24 Q (By Mr. Williams) I will just refer you quickly to the</p> <p>25 abstract on the first page of Exhibit No. 12, the</p>
<p style="text-align: right;">Page 163</p> <p>1 A I think usually we would want to look at it the other</p> <p>2 way.</p> <p>3 If you're looking at-- you wouldn't adjust for it</p> <p>4 necessarily. You might make sure to be aware that it's</p> <p>5 part of the causal-- part of the pathway.</p> <p>6 If you totally adjust for it, then it might make the</p> <p>7 relationship disappear, so perhaps it's not the best</p> <p>8 explanatory variable to use-- the best example, but the</p> <p>9 premise is that there can be a second variable that can</p> <p>10 be interfering with the relationship, which is why we</p> <p>11 adjust for things that can potentially be related to both</p> <p>12 the exposure and to the disease.</p> <p>13 Q And the second variable in the example that I used and</p> <p>14 that you used in your report was that variable of whether</p> <p>15 someone smokes?</p> <p>16 A Yes.</p> <p>17 Q In addition to the variable of their having matches</p> <p>18 often, right?</p> <p>19 A Yes.</p> <p>20 Q And one of the studies that you gave us this morning is a</p> <p>21 study written by Ulrik, U-L-R-I-K S. Kesmodel,</p> <p>22 K-E-S-M-O-D-E-L.</p> <p>23 Do you remember giving that one to us this morning?</p> <p>24 A Is this in the list?</p> <p>25 Q It was in the-- I'm sorry, it was identified on the list</p>	<p style="text-align: right;">Page 165</p> <p>1 Kesmodel study.</p> <p>2 About three-quarters of the way down, the abstract</p> <p>3 paragraph, it says, "Misclassification of confounders is</p> <p>4 an issue that needs special attention by researchers, as</p> <p>5 failure to measure accurately one or more strong</p> <p>6 confounders may seriously bias the observed results."</p> <p>7 Did I read that correctly from the abstract?</p> <p>8 A Yes.</p> <p>9 Q In the case of talcum powder use and the epidemiological</p> <p>10 studies that you've reviewed, a confounder is one that is</p> <p>11 related to ovarian cancer and perineal talc use, correct?</p> <p>12 A Correct, within that data set, yes.</p> <p>13 Q You agree that high body mass index, or BMI, is an</p> <p>14 established risk factor for ovarian cancer, true?</p> <p>15 A It is a risk factor, yes.</p> <p>16 Q And the WCRF document that we looked at this morning,</p> <p>17 that actually said that body mass index is probably a</p> <p>18 cause of ovarian cancer.</p> <p>19 Do you remember that this morning?</p> <p>20 MS. PARFITT: Objection.</p> <p>21 THE WITNESS: Yes.</p> <p>22 Q (By Mr. Williams) Body mass index is a measure of weight</p> <p>23 as compared to a measurement of height, right?</p> <p>24 A Yes.</p> <p>25 Q Now, the Continuous Update Project, for which you served</p>

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<p>1 as a panel member, has actually concluded that body mass 2 index is a probable cause. 3 That was Exhibit No.-- I believe it was Exhibit 4 No. 5 from this morning. 5 Do you remember that? 6 A I believe so. 7 Yes. 8 Q In May 2018, after you were hired by Plaintiffs' lawyers 9 in the talc litigation, you wrote an article concluding 10 that there was strong evidence that being overweight or 11 obese increased the risk for cancers. 12 Do you remember that? 13 That was Exhibit No. 9 that we talked about this 14 morning. 15 MS. PARFITT: Sorry, Exhibit No. 9? 16 MR. WILLIAMS: Yes. 17 THE WITNESS: The article-- 18 Q (By Mr. Williams) The article that had your picture on 19 it this morning, Exhibit No. 9 that we showed you-- 20 A Oh, press-- 21 Q It's 9. 22 On the second page in the first paragraph it says 23 that the latest report found strong evidence that being 24 overweight or obese increased the risk for a number of 25 things, and one of the things that is mentioned is cancer</p>	<p>1 A Yes. 2 Q Let me direct you to Page 250, which should be the second 3 page of the copy that was handed to you, the left-hand 4 column, first paragraph, last sentence-- hold on. I am 5 trying to find the citation. 6 Under the results section on that page, Page 250, do 7 you see that first paragraph? 8 A Yes. 9 Q The last sentence there says, "Talc use was associated 10 with higher body mass index and inversely associated with 11 current cigarette smoking." 12 Do you see that? 13 A Yes. 14 Q Talc use, this study found, was associated with higher 15 body mass index, true? 16 That's what it says? 17 A It doesn't give us any statistics on it, but if you look 18 at the table, you can see a slight association, yes. 19 Q Well, Table No. 1 does give us some information, correct? 20 MS. PARFITT: Objection; form. 21 THE WITNESS: It doesn't give us any P 22 values of how different it was. It doesn't give us 23 percents, but-- yeah. 24 Q (By Mr. Williams) Okay. And do you remember that in the 25 Cramer 1999 paper, that you rely upon, said that</p>
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<p>1 of the ovary, right? 2 MS. PARFITT: Objection. 3 THE WITNESS: Yes. 4 Q (By Mr. Williams) Okay. Talc use is associated with 5 higher body mass index, true? 6 A I have not investigated that. 7 I did not do a review on body mass index and talc 8 use. 9 Q The observation that talc use is associated with higher 10 body mass index is something that was noted in many of 11 the studies that you reviewed for purposes of your work, 12 right? 13 MS. PARFITT: Objection. 14 THE WITNESS: I didn't focus on body 15 mass index and talc use. 16 Q (By Mr. Williams) Let me ask-- 17 A If you have something to point to, we can look at it. 18 Q Let's look at the Gertig 2000 study. We have talked 19 about that one today. 20 This is going to be Exhibit No. 13. 21 (Exhibit No. 13 marked 22 for identification.) 23 //// 24 Q (By Mr. Williams) Do you have the Gertig study in front 25 of you, what we have marked as Exhibit No. 13?</p>	<p>1 characteristics, such as body odor or excessive 2 perspiration, might predispose to both talc use and 3 ovarian cancer, but adjusting for BMI should control for 4 those effects. 5 Do you remember that? 6 MS. PARFITT: Counsel, do you have a 7 copy of Cramer 1999 or could we get that? 8 MR. WILLIAMS: I am just asking if she 9 remembers it now, and if she doesn't-- 10 THE WITNESS: I don't recall. I would 11 have to look at it. 12 (Exhibit No. 14 marked 13 for identification.) 14 15 Q (By Mr. Williams) We will mark the Cramer 1999 study as 16 Exhibit No. 14. 17 I will direct your attention to the page that has in 18 the upper right-hand corner "355," the left-hand column, 19 second paragraph, the one that begins with, "Regarding 20 potential." 21 About midway down that paragraph it says, 22 "Characteristics such as body odor or excessive 23 perspiration might represent subtle constitutional 24 features that might predispose to both talc use and 25 ovarian cancer, but adjusting for BMI should control for</p>

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<p>1 these effects."</p> <p>2 Do you see that?</p> <p>3 A Yes.</p> <p>4 Q Does it make sense to you, separate and apart from these</p> <p>5 studies that I've shown you, that people who use talc on</p> <p>6 their bodies, including people who use talc in their</p> <p>7 perineal area, do so to absorb sweat and other moisture?</p> <p>8 A I didn't do a survey of why people use this.</p> <p>9 It's not clear that only people who sweat and have</p> <p>10 body odor are choosing to use body powders, so this isn't</p> <p>11 a substantiated sentence.</p> <p>12 I'm not quite clear.</p> <p>13 One statement it has about-- that it may predispose</p> <p>14 to ovarian cancer, I don't know of any literature</p> <p>15 associating body odor or perspiration for risk of or even</p> <p>16 early diagnosis of ovarian cancer, so I'm confused by</p> <p>17 that.</p> <p>18 Q Well, let me ask you to make an assumption then.</p> <p>19 If you make an assumption for me that BMI increases</p> <p>20 the risk for ovarian cancer, and you further make the</p> <p>21 assumption that more talc users have high BMI than</p> <p>22 nontalc users, do you believe that studies looking at</p> <p>23 talc and ovarian cancer should adjust for BMI?</p> <p>24 MS. PARFITT: Objection; form,</p> <p>25 misstates the evidence.</p>	<p>1 multivariate adjusted.</p> <p>2 If it was confounding from any of these variables</p> <p>3 that they adjusted for, you would see very big</p> <p>4 differences or much more marked than you see between</p> <p>5 age-adjusted relative risk and multivariate adjusted</p> <p>6 relative risk.</p> <p>7 Q Now, have you done the analysis to determine whether or</p> <p>8 not BMI was associated with greater talc use or whether</p> <p>9 BMI was associated as a confounder in terms of causing a</p> <p>10 higher odds ratio or risk ratio in the Gertig study?</p> <p>11 A Did I personally do any statistics on these? I didn't</p> <p>12 have the data to do the statistics, but you can see that</p> <p>13 its multivariate relative risk is so similar to</p> <p>14 age-adjusted relative risk. That means that it is not</p> <p>15 confounding in the data.</p> <p>16 Q Did you do that analysis as part of your work?</p> <p>17 MS. PARFITT: Objection; asked and</p> <p>18 answered.</p> <p>19 THE WITNESS: I am doing it right now.</p> <p>20 Q (By Mr. Williams) Did you--</p> <p>21 A Since you pointed it out.</p> <p>22 Q Did you do that analysis as part of your work--</p> <p>23 A When I presented relative risk, I tended to present the</p> <p>24 most adjusted relative risk I could find, I believe.</p> <p>25 That's what I tried to do.</p>
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<p>1 THE WITNESS: So we see in one study--</p> <p>2 I did not do a full review of all these studies, and I</p> <p>3 don't believe the data was available in all of them the</p> <p>4 way the Nurses' Health Study presented, which showed body</p> <p>5 mass index-- in all of the studies, and I didn't do a</p> <p>6 survey to look at the association between body mass index</p> <p>7 and talc use.</p> <p>8 I can see from these data in the Gertig study that</p> <p>9 it wasn't a confounder.</p> <p>10 They adjusted for it, but if you look at Table No. 2</p> <p>11 in the Gertig paper, the age-adjusted relative risk is</p> <p>12 very similar to the multivariate adjusted relative risk.</p> <p>13 The multivariate adjusted relative risk included</p> <p>14 body mass index, so this tells me that it's unlikely to</p> <p>15 be any or extremely little confounding when you see such</p> <p>16 a similar result for age-adjusted relative risk as you do</p> <p>17 for multivariate relative risk.</p> <p>18 Q Just so we are clear, you are looking right now at</p> <p>19 Exhibit No. 13, the Gertig study?</p> <p>20 A Sorry. Yes.</p> <p>21 Q Table No. 1 on Page 250, correct?</p> <p>22 A Table 1 and Table 2.</p> <p>23 Table 1 shows the association of BMI versus talc</p> <p>24 use.</p> <p>25 Table 2 shows the relative risk, age adjusted and</p>	<p>1 Q You reviewed three cohort studies in connection with your</p> <p>2 report, according to you, because you count Gates 2008</p> <p>3 and Gates 2010 as part of Gertig, correct? So that</p> <p>4 counts as one, right?</p> <p>5 A I believe those cases-- those two other cases that were</p> <p>6 in the second-- you are talking about the second Nurses'</p> <p>7 Health Study, the Gates 2008? I believe those 2010 were</p> <p>8 in the first one, but they're never quite clear.</p> <p>9 Q Let me start over.</p> <p>10 A Sorry.</p> <p>11 Q I don't want to quibble with you.</p> <p>12 You reviewed Gertig 2000, Houghton 2014, and</p> <p>13 Gonzalez 2016, correct?</p> <p>14 A That's correct.</p> <p>15 Q You also reviewed Gates 2008 and Gates 2010, correct?</p> <p>16 A Correct.</p> <p>17 Q Each one of those studies found no overall statistically</p> <p>18 significant association between perineal talc use and</p> <p>19 ovarian cancer?</p> <p>20 MS. PARFITT: Objection.</p> <p>21 Q (By Mr. Williams) I am not asking about serous invasive,</p> <p>22 as you went to before.</p> <p>23 I am talking about overall perineal task use.</p> <p>24 MS. PARFITT: Objection.</p> <p>25 Q (By Mr. Williams) Correct?</p>

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<p style="text-align: right;">Page 174</p> <p>1 MS. PARFITT: Objection; form.</p> <p>2 THE WITNESS: And the sample sizes</p> <p>3 were too small to be able to determine statistical</p> <p>4 significance with that level of relative risk.</p> <p>5 Q (By Mr. Williams) It was a consistent finding of those</p> <p>6 cohort studies that there was not a statistically</p> <p>7 significant association between perineal talc use overall</p> <p>8 and ovarian cancer, right?</p> <p>9 MS. PARFITT: Objection; form, asked</p> <p>10 and answered.</p> <p>11 THE WITNESS: The studies were not</p> <p>12 large enough.</p> <p>13 There were not enough cases to determine statistical</p> <p>14 significance or to have a statistically significant</p> <p>15 result.</p> <p>16 Q (By Mr. Williams) Is it your testimony that those</p> <p>17 studies found a statistically significant association</p> <p>18 overall between perineal talc use and ovarian cancer?</p> <p>19 MS. PARFITT: Objection; form.</p> <p>20 Counsel, that has been asked now about three or four</p> <p>21 times.</p> <p>22 I think she has given an answer.</p> <p>23 I know you don't like it, but she has responded.</p> <p>24 Q (By Mr. Williams) Are you saying that those studies</p> <p>25 found a statistically significant association between</p>	<p style="text-align: right;">Page 176</p> <p>1 able to tell us, as you sit here, how many of the</p> <p>2 case-control studies that you read and reviewed and are</p> <p>3 relying on in this case do not adjust for body mass</p> <p>4 index?</p> <p>5 MS. PARFITT: Objection; form.</p> <p>6 THE WITNESS: No, I did not count</p> <p>7 that.</p> <p>8 Q (By Mr. Williams) Why not?</p> <p>9 MS. PARFITT: I'm sorry, what was the</p> <p>10 question?</p> <p>11 Q (By Mr. Williams) Why not?</p> <p>12 MS. PARFITT: Objection.</p> <p>13 THE WITNESS: I was tasked to look at</p> <p>14 the overall association.</p> <p>15 I did not look at specific confounders for each of</p> <p>16 the studies.</p> <p>17 Q (By Mr. Williams) So if there were a confounder that</p> <p>18 could impact the answer to the question of whether</p> <p>19 perineal use of talcum powder causes cancer, you didn't</p> <p>20 look at it?</p> <p>21 MS. PARFITT: Objection; form,</p> <p>22 misstates the testimony.</p> <p>23 THE WITNESS: There could be</p> <p>24 confounding variables in any type of research that may or</p> <p>25 may not be available.</p>
<p style="text-align: right;">Page 175</p> <p>1 perineal talc use and ovarian cancer?</p> <p>2 MS. PARFITT: Objection, form.</p> <p>3 Again, a fifth time asked and answered.</p> <p>4 THE WITNESS: I am saying that they</p> <p>5 did not have a large enough sample size to find a</p> <p>6 statistically significant association.</p> <p>7 Q (By Mr. Williams) Identify for us on the record any</p> <p>8 cohort study that concluded that there was a</p> <p>9 statistically significant overall association between</p> <p>10 talc and ovarian cancer.</p> <p>11 A I can't identify any.</p> <p>12 Q In forming your opinions in this litigation, did you take</p> <p>13 note of the fact that each of those cohort studies</p> <p>14 accounted for body mass index or BMI?</p> <p>15 A I believe I did not go through specific-- I am sure I</p> <p>16 didn't go through specific confounding variables.</p> <p>17 I just noted that they adjusted for potential</p> <p>18 confounders and presented the most adjusted variable.</p> <p>19 Q Your written report does not take note of the fact that</p> <p>20 each of the cohort studies you reviewed accounted for</p> <p>21 body mass index, did it?</p> <p>22 MS. PARFITT: Objection; form.</p> <p>23 THE WITNESS: No, I didn't note one</p> <p>24 particular variable for adjustment.</p> <p>25 Q (By Mr. Williams) Without reviewing the studies, are you</p>	<p style="text-align: right;">Page 177</p> <p>1 I noticed in the Gertig study, the data that we just</p> <p>2 talked about, that body mass index was not a confounder,</p> <p>3 so that gives me some-- at least in one data set, that it</p> <p>4 wasn't an issue, nor would the other variables adjusted</p> <p>5 for have been confounders because the multivariate</p> <p>6 relative risk is so similar to the age-adjusted relative</p> <p>7 risk.</p> <p>8 Q (By Mr. Williams) Did the Gertig study conclude what you</p> <p>9 just said?</p> <p>10 A I think I just presented it.</p> <p>11 Q While you are reading, Doctor, I just want to be clear</p> <p>12 with what my question is.</p> <p>13 My question is:</p> <p>14 Did-- strike that.</p> <p>15 Where in the Gertig study did the Gertig study say</p> <p>16 or conclude that BMI is not a confounder for talc use?</p> <p>17 A It's a general epidemiologic principle that if you see</p> <p>18 similar results for the multivariate relative risk that</p> <p>19 you see with just a-- either an unadjusted or in this</p> <p>20 case age-adjusted relative risk, that the confounding</p> <p>21 variables that were adjusted for in the multivariate are</p> <p>22 unlikely to be confounders.</p> <p>23 If they were, the data would look different.</p> <p>24 Q Have you completed your answer?</p> <p>25 A Yes.</p>

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<p style="text-align: right;">Page 178</p> <p>1 Q Did the Gertig study expressly state that BMI is not a 2 confounder for talc? 3 MS. PARFITT: Objection; asked and 4 answered. 5 THE WITNESS: I don't see that they 6 said that, but the data are showing it to me. 7 Q (By Mr. Williams) In forming your opinions in this 8 litigation, you did not do any analysis of whether the 9 studies that you relied upon adjusted for body mass 10 index, correct? 11 A I didn't enumerate that, no. 12 Q I would like to ask you about another type of study, the 13 meta and the pooled analyses. 14 You rely significantly on those study types, 15 correct? 16 A That's correct. 17 Q For the meta and the pooled analysis, the ones with the 18 combined data, you believe that the summary relative 19 risks for any talc use versus no talc use were 20 consistent, true? 21 A Yes, I want to look at the-- 22 Q For reference, in your report, Exhibit No. 2 at Page 56. 23 A I want to look at the papers too. 24 Q I am just asking about your report, not the papers yet. 25 As far as your report is concerned, you believe that</p>	<p style="text-align: right;">Page 180</p> <p>1 case-control studies, the eight case-control studies, 2 plus three previous and published studies. 3 Q You did not perform your own meta-analysis, right? 4 A No, I didn't. 5 Q One of the reasons you did not perform your own 6 meta-analysis was because you believe that there were 7 two, in your words, excellent meta-analyses that had 8 recently been published, Penninkilampi and Berge, 9 correct? 10 A Correct. 11 Q "Penninkilampi" is spelled P-E-N-N-I-N-K-I-L-A-M-P-I. 12 That was from 2018, correct? 13 A Yes. 14 Q And the Berge analysis, B-E-R-G-E, was from 2017? 15 A Yes. 16 Q You believe that those two studies are consistent with 17 one another? 18 A Yes, they have very similar results. 19 Q Do you believe they support your opinion in the case that 20 perineal talcum powder can cause ovarian cancer? 21 A Yes. 22 Q Let me show you the Penninkilampi study. We'll mark it 23 as Exhibit No. 15, I believe. 24 (Exhibit No. 15 marked 25 for identification.)</p>
<p style="text-align: right;">Page 179</p> <p>1 the summary of relative risks for any talc use versus no 2 talc use are consistent, right? 3 A And where are you, Page 56? 4 Q Page 56, the top paragraph, middle of the paragraph, 5 sentence starting with, "The summary relative risks," 6 about four lines down. 7 A "Were quite consistent," yes, I wrote that. 8 Q Are there other ways in which the meta and the pooled 9 analyses are consistent, in your opinion? 10 A I am not sure what you're asking. 11 Q Well, in addition to the notion that the relative risks 12 were quite consistent, in your opinion, across the meta 13 and the pooled analyses, were there any other ways in 14 which those meta and pooled analyses were consistent, any 15 other hallmarks of a consistency, other than the relative 16 risk rates that you found notable? 17 A I think if you could give some examples-- one-- 18 Q I am just asking you for your expert opinion. 19 A One thing that is consistent is that for the two 20 meta-analyses that are most recent, which is why I put 21 most weight on them, they have all of the previous 22 studies included, is that they included the same study, 23 so that's similar between those two meta-analyses, 24 Penninkilampi and Berge. 25 The pooled analysis was a subset of those</p>	<p style="text-align: right;">Page 181</p> <p>1 2 Q (By Mr. Williams) Do you recognize Exhibit No. 15, 3 Penninkilampi 2018, as one of the two studies that you 4 described as excellent and supportive of your opinions? 5 A Yes. 6 Q Do you know the source or sources of funding for this 7 paper? 8 A No, I don't. 9 Q Do you personally know who the author is? 10 A No, I don't. 11 Q Do you know what, if any, conflicts of interest any of 12 the authors may have? 13 A I am just looking to see. 14 They claim no conflicts of interest. 15 Q Do you know whether some of the authors are serving as 16 consultants to Plaintiffs' counsel in this litigation? 17 A No, I don't. 18 Q Do you have any criticisms of the Penninkilampi 2018 19 meta-analysis? 20 MS. PARFITT: Objection; form. 21 THE WITNESS: I think the only issue 22 that I see are based on all of the-- all of the 23 meta-analyses had this issue that depends on what results 24 were available from the source studies, so if there 25 weren't many studies that could do-- that could look at</p>

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<p style="text-align: right;">Page 182</p> <p>1 subgroups, for example, or if there weren't enough--</p> <p>2 wasn't enough information to do dose response-- but by</p> <p>3 doing a meta-analysis, you have the best chance of being</p> <p>4 able to look at these because in the individual study</p> <p>5 those variables are-- the numbers of people within</p> <p>6 particular subgroups is going to be too small to be able</p> <p>7 to do an analysis.</p> <p>8 Q (By Mr. Williams) Did you do an independent verification</p> <p>9 of the data that the Penninkilampi study reports in--</p> <p>10 strike that.</p> <p>11 Did you do an independent verification that the data</p> <p>12 that this study reports is indeed accurate?</p> <p>13 A Did I do a meta-analysis myself on statistics? I did</p> <p>14 not.</p> <p>15 Q No, just whether the data that is reported accurately</p> <p>16 reflects what was reported in the study's records.</p> <p>17 A So there was a supplementary data table for this, I</p> <p>18 assume.</p> <p>19 I am pretty sure I looked at that and then compared</p> <p>20 the relative risk that I abstracted onto my data table,</p> <p>21 and I believe they were similar, but I don't see</p> <p>22 supplementary data here.</p> <p>23 Q Take a look at Page 46 of the document in the lower</p> <p>24 left-hand corner, Page 46 of Exhibit No. 15.</p> <p>25 Do you see that the Penninkilampi study includes,</p>	<p style="text-align: right;">Page 184</p> <p>1 correctly that are implemented.</p> <p>2 What I'm most intrigued by, all the cohort studies I</p> <p>3 reviewed, all seven of them, come up with just about the</p> <p>4 same overall relative risk of ever-use of talcum powder</p> <p>5 products and risk of ovarian cancer. It is consistently</p> <p>6 1.25 to 1.3, and that tells me that this is a robust</p> <p>7 finding because you see it in so many of these studies.</p> <p>8 Q (By Mr. Williams) Would you expect the association for</p> <p>9 long-term perineal talc use, say more than ten years, to</p> <p>10 be greater than, the same, or less than the association</p> <p>11 for any talc use, which could include a single use?</p> <p>12 A I would say it depends on what the individual study had</p> <p>13 in terms of sample size within categories.</p> <p>14 It really depends on sample size, and it depends on</p> <p>15 what the data look like.</p> <p>16 It's a difficult question to answer.</p> <p>17 Q Take a look at Page 46, Figure No. 2 of the Penninkilampi</p> <p>18 study, Exhibit No. 15.</p> <p>19 Do you see the explanation of the tables in Figure</p> <p>20 No. 2?</p> <p>21 Do you see that Table A refers to odds ratios for</p> <p>22 any perineal talc use?</p> <p>23 A Yes.</p> <p>24 Q And the odds ratio for the combined data, the data for</p> <p>25 any talc use in Table A, is 1.31?</p>
<p style="text-align: right;">Page 183</p> <p>1 for each study, a purported odds ratio, a lower limit and</p> <p>2 an upper limit?</p> <p>3 A Yes.</p> <p>4 Q Did you go back to the individual studies to verify that</p> <p>5 the numbers were recorded accurately?</p> <p>6 A I didn't compare the lower and upper limit of the</p> <p>7 confidence interval.</p> <p>8 Q Would it be important to you, in determining that a study</p> <p>9 is excellent, that the authors accurately report the odds</p> <p>10 ratio and the confidence intervals?</p> <p>11 A I think that would be useful, but for a meta-analysis,</p> <p>12 the data that goes into it, to my knowledge, are the odds</p> <p>13 ratios and the sample size, so I am not sure what</p> <p>14 variable-- which particular study you're talking about is</p> <p>15 not reported correctly.</p> <p>16 Q I am asking you whether it's important, not just whether</p> <p>17 it's notable.</p> <p>18 Would it be important to you, in determining--</p> <p>19 concluding that a study is excellent, that the authors</p> <p>20 accurately report the odds ratios and the confidence</p> <p>21 intervals; that is, if they get it wrong, that's not the</p> <p>22 sign of an excellent study, right?</p> <p>23 MS. PARFITT: Objection; form.</p> <p>24 THE WITNESS: I think in many studies</p> <p>25 there may be occasional data that are transformed not</p>	<p style="text-align: right;">Page 185</p> <p>1 Do you see that?</p> <p>2 A Yes.</p> <p>3 Q Now look at Table B.</p> <p>4 Do you see that this table refers to long-term</p> <p>5 perineal talc use?</p> <p>6 A Yes.</p> <p>7 Q The odds ratio for that combined data, the data for</p> <p>8 long-term use, is 1.25.</p> <p>9 Do you see that?</p> <p>10 A Yes.</p> <p>11 Q So as between Penninkilampi's reported overall</p> <p>12 association for any talc use, on the one hand, and its</p> <p>13 reporting for long-term talc use on the other, which one</p> <p>14 reflects a higher risk rate or odds ratio?</p> <p>15 A I would say they're very similar, 1.31 and 1.25, because</p> <p>16 the confidence interval include both, so the confidence</p> <p>17 interval in the top, 1.24 to 1.39, also includes the</p> <p>18 bottom odds ratio of 1.25. That tells me they're very</p> <p>19 similar.</p> <p>20 Q Doctor, I am just asking you a simple question.</p> <p>21 I asked you which one reflects a higher risk rate.</p> <p>22 MS. PARFITT: Objection; form, asked</p> <p>23 and answered.</p> <p>24 THE WITNESS: I am answering as an</p> <p>25 epidemiologist.</p>

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<p>1 We would see those answers as quite similar.</p> <p>2 Q (By Mr. Williams) So epidemiologists would say that 1.31</p> <p>3 and 1.25, with the confidence intervals there, are the</p> <p>4 same?</p> <p>5 A I wouldn't say they're the same.</p> <p>6 Q So which one--</p> <p>7 MS. PARFITT: Counsel, please let her</p> <p>8 finish.</p> <p>9 Thank you.</p> <p>10 THE WITNESS: We wouldn't say they're</p> <p>11 the same, but we would state they could be similar.</p> <p>12 1.31 is clearly larger than 1.25, but they could</p> <p>13 be-- because of those confidence intervals, they could be</p> <p>14 similar numbers.</p> <p>15 Q (By Mr. Williams) When you evaluated the Penninkilampi</p> <p>16 study, did you take note that the authors omitted certain</p> <p>17 cohort data?</p> <p>18 MS. PARFITT: Objection; form.</p> <p>19 THE WITNESS: I noted that they</p> <p>20 included one paper from each study, which is really</p> <p>21 important.</p> <p>22 If you include more than one paper from each study,</p> <p>23 then you're over-counting or counting cases or noncases a</p> <p>24 second time.</p> <p>25 It's really important to only have one cohort</p>	<p>1 misstates her testimony.</p> <p>2 THE WITNESS: I would say because of</p> <p>3 the variable used, it was reasonable that they picked the</p> <p>4 Gonzalez, the first one.</p> <p>5 If the data had been collected in an identical way,</p> <p>6 then the third one would have been incorporated.</p> <p>7 Q (By Mr. Williams) Did the study explain that that was</p> <p>8 the reason why they omitted the Gates 2010 study?</p> <p>9 A I can't remember.</p> <p>10 I think they had an appendix.</p> <p>11 They talk about an appendix here with their</p> <p>12 rationale.</p> <p>13 Q We can check it later, but as you sit here today, can you</p> <p>14 remember any reference to--</p> <p>15 A I can't recall--</p> <p>16 Q Let me finish the question, if I could.</p> <p>17 Doctor, can you remember any reference, as you sit</p> <p>18 here, to the notion that they noted, in Penninkilampi,</p> <p>19 that they were not using the data from Gates 2010?</p> <p>20 MS. PARFITT: If you need to consult</p> <p>21 the document, please do.</p> <p>22 MR. WILLIAMS: My question is not</p> <p>23 asking her to read it.</p> <p>24 Q (By Mr. Williams) My question is whether you remember</p> <p>25 it?</p>
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<p>1 represented in each of these meta-analyses.</p> <p>2 Q (By Mr. Williams) But if there had been additional</p> <p>3 cohorts after the first cohort, wouldn't it make sense to</p> <p>4 use the last one rather than the first?</p> <p>5 MS. PARFITT: Objection; form.</p> <p>6 THE WITNESS: I think you are talking</p> <p>7 about the Nurses' Health Study.</p> <p>8 Q (By Mr. Williams) I am.</p> <p>9 A Whether they included the first one or the third one,</p> <p>10 because the second one wouldn't do them any good. There</p> <p>11 are only 200 cases. We don't know how they picked those.</p> <p>12 The third one, as I mentioned earlier, the problem</p> <p>13 with the third one is it used a different comparison to--</p> <p>14 than the first one.</p> <p>15 They are not comparing no-use versus ever-use.</p> <p>16 They're comparing no-use plus less-than-once-a-week</p> <p>17 versus higher levels, so you want to compare, as much as</p> <p>18 possible, nonusers versus users, which is-- they are</p> <p>19 trying to look at any ovarian-- sorry, any perineal talc</p> <p>20 use in the Category A would be more accurate to use the</p> <p>21 first Nurses' Health Study.</p> <p>22 Q Should I take your last answer to mean that you believe</p> <p>23 it is a good thing that the Gates 2000 study was omitted</p> <p>24 from the Penninkilampi analysis?</p> <p>25 MS. PARFITT: Objection; form,</p>	<p>1 MS. PARFITT: Without reading the</p> <p>2 document, do you recall?</p> <p>3 THE WITNESS: I don't recall.</p> <p>4 Q (By Mr. Williams) Take a look at Figure No. 2, Table C</p> <p>5 of Page 46 of that study.</p> <p>6 Do you see that it describes the purported</p> <p>7 association for increased risk of serous ovarian cancers?</p> <p>8 A Yes.</p> <p>9 Q And that's reporting the original Berge study from 2010,</p> <p>10 right?</p> <p>11 A 2000? Berge 2000?</p> <p>12 Q Excuse me, not 2010. Pardon me.</p> <p>13 2000-- Berge 2000?</p> <p>14 A Yes.</p> <p>15 Q As you sit there, you don't know-- you don't recall any</p> <p>16 explanation for the omission of the Gates 2010 data,</p> <p>17 right?</p> <p>18 MS. PARFITT: Objection; form.</p> <p>19 MR. WILLIAMS: I'm sorry, did I get an</p> <p>20 answer to that one?</p> <p>21 MS. PARFITT: No. She-- I think she</p> <p>22 is reading the document.</p> <p>23 THE WITNESS: Sorry.</p> <p>24 MS. PARFITT: Take your time.</p> <p>25 MR. WILLIAMS: My question-- well,</p>

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<p>1 hold on.</p> <p>2 Counsel, that just eats up the time.</p> <p>3 Q (By Mr. Williams) I am asking-- Doctor--</p> <p>4 MS. PARFITT: Counsel, you asked--</p> <p>5 MR. WILLIAMS: Let me finish--</p> <p>6 MS. PARFITT: Let me finish.</p> <p>7 You asked her in the middle of a question-- she</p> <p>8 hasn't answered it.</p> <p>9 Your question is right there.</p> <p>10 She hadn't answered it.</p> <p>11 She is reading the document. That's reflected on</p> <p>12 the camera.</p> <p>13 Give her-- if you want an answer to the question,</p> <p>14 give her an opportunity--</p> <p>15 Q (By Mr. Williams) Here is the problem, Doctor--</p> <p>16 MR. WILLIAMS: Are you done, Counsel?</p> <p>17 MS. PARFITT: I am.</p> <p>18 Q (By Mr. Williams) Here is the problem, Doctor:</p> <p>19 If I ask a question that is separate and apart from</p> <p>20 the document in front of you, and you choose to just read</p> <p>21 the entire document, all of our time is lost, so when I</p> <p>22 specifically ask you what you remember as you sit there,</p> <p>23 I would ask you not to read the document because that's</p> <p>24 not part of the question.</p> <p>25 Is that okay with you?</p>	<p>1 considered improper-- improper methodology.</p> <p>2 Usually these meta-analyses, and I believe they had</p> <p>3 it too, usually they will have supplementary data that's</p> <p>4 available also that will give more of their methods and</p> <p>5 the search terms, and I don't see that in what you've</p> <p>6 provided here today.</p> <p>7 Q (By Mr. Williams) Let me ask you to look at the Berge</p> <p>8 study from 2017. We will mark that as Exhibit No. 16.</p> <p>9 (Exhibit No. 16 marked</p> <p>10 for identification.)</p> <p>11</p> <p>12 Q (By Mr. Williams) Do you recognize Exhibit No. 16, which</p> <p>13 is the Berge 2017 study, as the other of the two</p> <p>14 meta-analyses that you described as excellent?</p> <p>15 A Yes.</p> <p>16 Q Please turn to Page 9 of the study.</p> <p>17 I direct your attention to the left-hand column, the</p> <p>18 last paragraph before "Acknowledgments."</p> <p>19 Do you see that?</p> <p>20 A Yes.</p> <p>21 Q The Berge study says, "Several aspects of our results,</p> <p>22 including the heterogeneity of results between</p> <p>23 case-control and cohort studies and the lack of a dose</p> <p>24 response with duration and frequency of use, however, do</p> <p>25 not support a causal interpretation of the association."</p>
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<p>1 MS. PARFITT: Counsel, that's actually</p> <p>2 not okay as a question.</p> <p>3 If the question is asking if this is a memory</p> <p>4 contest-- when she has the document in front of her, why</p> <p>5 aren't you allowing her to refer to the document?</p> <p>6 It's not a memory contest.</p> <p>7 Q (By Mr. Williams) Here is my question, Doctor:</p> <p>8 As you sit here, do you remember, one way or the</p> <p>9 other, whether the Penninkilampi study explains why it</p> <p>10 omitted any reference to the data from the Gates 2010</p> <p>11 report--</p> <p>12 MS. PARFITT: And I'm going to again</p> <p>13 object.</p> <p>14 Counsel, if she needs to look-- are you suggesting</p> <p>15 she can't look at the document to refresh her</p> <p>16 recollection? Is that what you want the record to</p> <p>17 reflect.</p> <p>18 Q (By Mr. Williams) You may answer, Doctor.</p> <p>19 MS. PARFITT: Take your time, Doctor.</p> <p>20 THE WITNESS: Looking at the methods</p> <p>21 here, I don't see that they've mentioned here why they</p> <p>22 chose particular studies.</p> <p>23 I do know that it's standard for meta-analysis to</p> <p>24 only include one study from a cohort.</p> <p>25 If you included more than one, it would be</p>	<p>1 Do you see that conclusion?</p> <p>2 A Yes, I do.</p> <p>3 Q The author's conclusion that the reported association did</p> <p>4 not support a causal interpretation, is the opposite of</p> <p>5 the conclusion that you would come up with in this case,</p> <p>6 correct?</p> <p>7 MS. PARFITT: Objection; form.</p> <p>8 THE WITNESS: That's correct.</p> <p>9 Q (By Mr. Williams) If you would, keep the Berge 2017</p> <p>10 paper out.</p> <p>11 I will also ask you to refer for a moment to your</p> <p>12 own report, which is Exhibit No. 2, and specifically Page</p> <p>13 75.</p> <p>14 There is a table, Table No. 3, of data that you</p> <p>15 compiled about the various meta-analyses.</p> <p>16 Do you see that table?</p> <p>17 A Yes.</p> <p>18 Q And Berge 2017 is the second one that is referenced?</p> <p>19 A Yes.</p> <p>20 Q The right-most column of your table is called, "Dose</p> <p>21 response," correct?</p> <p>22 A Yes.</p> <p>23 Q And I'm going to talk a little more about dose response</p> <p>24 later, but for now can we agree that under the "Dose</p> <p>25 response" column for Berge 2017, you wrote, "Yes," for</p>

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<p style="text-align: right;">Page 194</p> <p>1 duration and frequency-- did you write that?</p> <p>2 A Yes.</p> <p>3 Q And then you wrote a colon, and you went on to reflect</p> <p>4 that each ten-year increase in genital talc use was</p> <p>5 associated with a 16 percent increase in relative risk,</p> <p>6 and each increase of one application per week was</p> <p>7 associated with a five percent increase in relative risk.</p> <p>8 Do we have that right?</p> <p>9 A Yes.</p> <p>10 Q Now, if you would, please, turn back to the Berge study.</p> <p>11 Can you just-- we couldn't find it. Maybe you can,</p> <p>12 and this one I do want you to look through it.</p> <p>13 Would you please point out where the figures we just</p> <p>14 discussed from your table are actually reflected in the</p> <p>15 study?</p> <p>16 I'm sure it's there. We just couldn't find it.</p> <p>17 A I am not finding it.</p> <p>18 MS. PARFITT: Counsel, I can make it</p> <p>19 quicker, so we can save on time.</p> <p>20 Do you want me to show her where it is or have her</p> <p>21 keep looking?</p> <p>22 MR. WILLIAMS: I actually prefer that</p> <p>23 that not be what we do.</p> <p>24 MS. PARFITT: All right. I am just</p> <p>25 trying to move time along.</p>	<p style="text-align: right;">Page 196</p> <p>1 MS. PARFITT: Counsel, there are.</p> <p>2 If I can help, there's two Berge papers. One talks</p> <p>3 about the dose response and one does not, and I think you</p> <p>4 handed her the copy about-- that does not address the</p> <p>5 dose response, and the one she has in her binder</p> <p>6 addresses the dose response, both 2018 and very</p> <p>7 confusing, but--</p> <p>8 MR. WILLIAMS: So they are two</p> <p>9 different studies entirely?</p> <p>10 MS. PARFITT: No, they are actually</p> <p>11 very, very close, but one addressed the dose response and</p> <p>12 one did not.</p> <p>13 One, Doctor-- just for clarify, the one that</p> <p>14 Mr. McTiernan has in her notebook and that you all have</p> <p>15 in your reference material is Exhibit No.-- Reference</p> <p>16 No.-- what is that?</p> <p>17 THE WITNESS: 35.</p> <p>18 MS. PARFITT: 35 in the notebook,</p> <p>19 which is the Berge study that deals with the dose</p> <p>20 response.</p> <p>21 The one you handed her is the Berge that does not</p> <p>22 address the dose response or indicated there was no</p> <p>23 trend.</p> <p>24 MR. WILLIAMS: Let's mark for the</p> <p>25 record the one that Dr. McTiernan has in her hand as</p>
<p style="text-align: right;">Page 195</p> <p>1 Q (By Mr. Williams) If you could turn to Page 6 of the</p> <p>2 Berge meta-analysis, in the left-hand side, Table No. 3</p> <p>3 there, it says there-- it has a table in Table No. 3 that</p> <p>4 lists the duration of frequency, "Ever use of genital</p> <p>5 talc - results of meta-analysis."</p> <p>6 Do you see that?</p> <p>7 A Yes, Table No. 3?</p> <p>8 Q Right.</p> <p>9 It says, "Duration, ten years," and then there's a</p> <p>10 risk ratio of 0.97, with a confidence interval that drops</p> <p>11 below 1.0.</p> <p>12 Do you see that?</p> <p>13 A It looks like you have a different version than I have.</p> <p>14 Q Do I?</p> <p>15 A Yeah.</p> <p>16 Yours is-- my table looks different.</p> <p>17 That's odd.</p> <p>18 Q Are you looking at the-- I see, you are comparing-- just</p> <p>19 for the record, you are comparing what we gave you as</p> <p>20 Exhibit No. 16 with something in a notebook.</p> <p>21 Which notebook are you looking in?</p> <p>22 A My data-- all the references that I used.</p> <p>23 Q Okay.</p> <p>24 A I am just wondering--</p> <p>25 Q Are there different versions of it?</p>	<p style="text-align: right;">Page 197</p> <p>1 Exhibit No. 16A.</p> <p>2 MS. PARFITT: Very good.</p> <p>3 (Exhibit No. 16A marked</p> <p>4 for identification.)</p> <p>5</p> <p>6 MR. WILLIAMS: Do you happen to have</p> <p>7 another copy of that one?</p> <p>8 MS. PARFITT: Yeah, I can check.</p> <p>9 MR. WILLIAMS: Thank you.</p> <p>10 Q (By Mr. Williams) If you could look at Exhibit No. 16,</p> <p>11 and turn to Page 7.</p> <p>12 A So we are back to the other one?</p> <p>13 Q The original--</p> <p>14 A That I did not reference?</p> <p>15 Q Exhibit No. 16.</p> <p>16 Do you have that in front of you?</p> <p>17 A Page 7?</p> <p>18 Q Page 7, the right-hand column.</p> <p>19 Do you see in the right-hand column it says, "The</p> <p>20 presence or absence of a dose response is an important</p> <p>21 aspect to consider in assessing the plausibility of the</p> <p>22 causal nature of an association observed in a</p> <p>23 meta-analysis"?</p> <p>24 Did I read that right?</p> <p>25 A Yes, and the other version says the same thing.</p>

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<p style="text-align: right;">Page 198</p> <p>1 Q Okay. It goes on to say, I believe in both versions, 2 "Although the numbers of studies included in the analysis 3 of duration and frequency of genital talc use was not 4 very large, and the exclusion of the reference category 5 from the dose response analysis might have reduced the 6 power of this analysis, the lack of a dose response -- 7 irrespective on an analytical approach chosen to combine 8 categorical results across studies -- is a potentially 9 important and novel contribution of this meta-analysis." 10 Did I read that right? 11 A Except the next version does not say, "lack of"-- if you 12 read the paragraph from 16A, it does not say "lack of 13 dose response." 14 You have that right there. 15 They have taken out that. 16 They must have replaced this table with a corrected 17 table, because that does show dose response in Table 18 No. 3. 19 Q So Table No. 3 in the two different versions of the Berge 20 study are different? 21 A Yes. 22 That's why I was so confused. 23 My data and my table was identical-- I abstracted 24 this. 25 MS. PARFITT: "This" being 16A?</p>	<p style="text-align: right;">Page 200</p> <p>1 MS. PARFITT: Objection; form. 2 THE WITNESS: And I tend to look at 3 data, not necessarily what somebody has written as their 4 conclusion. 5 The data to me show that there is an increased risk 6 of ovarian cancer with use of talcum powder products, and 7 I think their data show it very clearly, and they have 8 shown dose response relationships as well. 9 Q (By Mr. Williams) My question to you is a little bit 10 different. 11 My question is: 12 You disagree-- strike that. 13 You disagree with the conclusion reached by the 14 authors of the Berge study in that last sentence of their 15 report that finds heterogeneity between the results of 16 case-control and cohort studies, correct? 17 MS. PARFITT: Objection; form, 18 misstates her testimony. 19 THE WITNESS: So you are only asking 20 about the first part of that sentence not the causal 21 interpretation, but the first part; is that correct? 22 Q (By Mr. Williams) I am asking about the entirety of the 23 sentence. 24 A The entirety of the sentence? 25 So yes, there was heterogeneity between the</p>
<p style="text-align: right;">Page 199</p> <p>1 THE WITNESS: 16A, the version I used, 2 and that's the version that was on the website and my 3 library. 4 Q (By Mr. Williams) Did you at any time read this study 5 that was marked as Exhibit No. 16? 6 A No. 7 Q And how did you access the version at 16A? 8 A This one I would have gotten from my Fred Hutch library. 9 Q Let me have you look at Exhibit No. 16A. 10 Do you have Page 9 in front of you? 11 Can you turn to that page, just before the 12 acknowledgments? 13 A Okay. 14 Q And this is the conclusion paragraph. 15 Do you see that it begins, "In conclusion"? 16 A Yes. 17 Q In the 16A version that you have in front of you they 18 wrote, "Several aspects of our results, including the 19 heterogeneity of results between case-control and cohort 20 studies, however, do not support a causal interpretation 21 of the association." 22 Do you see that? 23 A Yes. 24 Q And that was the conclusion of the Berge study from 2017 25 in both versions 16 and 16A, correct?</p>	<p style="text-align: right;">Page 201</p> <p>1 case-control and cohort studies, but no, I do not think 2 that that detracts from the causal association. 3 Q What was the heterogeneity and the results between the 4 case-control and the cohort studies that you observed? 5 A There was a smaller increase in risk with the 6 case-control studies. 7 Q How much smaller? 8 A Quite a bit. 9 The relative risk was 1.02 in the cohort studies, 10 1.26 in the case-control studies. 11 Q And you conclude, based upon your own analysis, totally 12 separate from the Berge study-- you conclude, based on 13 your own analysis, that that disparity, 1.02 for the 14 cohorts, 1.26 for the case-control studies, constitutes 15 heterogeneity between those two types of studies? 16 MS. PARFITT: Objection; misstates her 17 testimony. 18 She says she relied on the data. 19 MR. WILLIAMS: Counsel, I would ask 20 you not to coach. 21 MS. PARFITT: I am not coaching. 22 Let the record reflect I am not coaching. I am 23 making it clear. 24 THE WITNESS: I agreed that there's 25 heterogeneity between those two sets of results, but that</p>

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<p style="text-align: right;">Page 202</p> <p>1 it does not subtract from the causal interpretation.</p> <p>2 The other thing I note when I look at a figure like</p> <p>3 this, Figure No. 2 in that Berge paper, that almost all</p> <p>4 of the relative risks are to the right of the line; "the</p> <p>5 line" being the line where the relative risk would be one</p> <p>6 or no effect.</p> <p>7 It's unusual to see so many studies with the</p> <p>8 relative risk over on the right side.</p> <p>9 I review a lot of meta-analyses, so this is unusual</p> <p>10 to see that level of consistency.</p> <p>11 Q (By Mr. Williams) So just so we're clear, you disagree</p> <p>12 with the second half, the second clause of the final</p> <p>13 sentence in the Berge study, but you agree with the first</p> <p>14 portion, correct?</p> <p>15 MS. PARFITT: Objection; form,</p> <p>16 misstates her testimony.</p> <p>17 THE WITNESS: I agree that the cohort</p> <p>18 studies have lower relative risks than do the</p> <p>19 case-control studies, yes.</p> <p>20 Q (By Mr. Williams) And you agree that that makes them</p> <p>21 heterogeneous, correct?</p> <p>22 MS. PARFITT: Objection; form.</p> <p>23 Q (By Mr. Williams) Those two different types of studies?</p> <p>24 MS. PARFITT: Objection; form.</p> <p>25 THE WITNESS: That's part of the</p>	<p style="text-align: right;">Page 204</p> <p>1 A Ms. Parfitt sent them.</p> <p>2 Q Did she--</p> <p>3 A I am trying to remember if there was a website as well.</p> <p>4 Q Do you know how she obtained them?</p> <p>5 MS. PARFITT: Objection; form.</p> <p>6 THE WITNESS: I do not know.</p> <p>7 Q (By Mr. Williams) Are you relying on the Taher 2018</p> <p>8 study for your opinion in this litigation?</p> <p>9 A I am not relying on the study, but it did add to my-- it</p> <p>10 does substantiate my opinion.</p> <p>11 It's very similar results to what we saw in the</p> <p>12 other meta-analyses.</p> <p>13 Q Is the Taher 2018 article peer-reviewed?</p> <p>14 A Not to my knowledge, but I don't know what process it</p> <p>15 went through to get to this point.</p> <p>16 Q Do you know one way or the other whether it has been</p> <p>17 accepted for publication?</p> <p>18 A I don't know.</p> <p>19 Q Do you know the source or sources of funding for the</p> <p>20 Taher 2018 article?</p> <p>21 A I think it said Health Canada, but--</p> <p>22 Q Other than the reference to Health Canada-- it references</p> <p>23 a contract with Health Canada.</p> <p>24 Other than that, do you have any knowledge as to the</p> <p>25 sources of funding?</p>
<p style="text-align: right;">Page 203</p> <p>1 definition of "heterogeneity," is to see differences.</p> <p>2 Q (By Mr. Williams) Let me ask you some questions about</p> <p>3 the Taher 2018 study.</p> <p>4 We will mark that study as Exhibit No. 17.</p> <p>5 (Exhibit No. 17 marked</p> <p>6 for identification.)</p> <p>7</p> <p>8 Q (By Mr. Williams) The Taher 2018 study is not one of the</p> <p>9 articles that you originally included in your reference</p> <p>10 list, right?</p> <p>11 A That's correct.</p> <p>12 It was made public after my report was submitted.</p> <p>13 Q It is included in the additional materials to Dr. Anne</p> <p>14 McTiernan, a listing that we marked earlier today?</p> <p>15 A Yes.</p> <p>16 Q Have you read the entire transcript?</p> <p>17 A Yes, I have.</p> <p>18 Q Did you have access to this article before it was</p> <p>19 published?</p> <p>20 A It's not published. It's a draft manuscript.</p> <p>21 Q Do you have access to the appendixes or supplemental</p> <p>22 tables that are referenced in the publication?</p> <p>23 A Yes.</p> <p>24 I don't have them with me, but I did have access.</p> <p>25 Q How did you have access to them?</p>	<p style="text-align: right;">Page 205</p> <p>1 MS. PARFITT: Objection; form.</p> <p>2 THE WITNESS: All I know is source of</p> <p>3 funding is Health Canada, what it says in the paper.</p> <p>4 Q (By Mr. Williams) Do you personally know any of the</p> <p>5 authors who are listed on the first page?</p> <p>6 A No, I don't.</p> <p>7 Q Have you discussed your opinion on talc and ovarian</p> <p>8 cancer with any of those authors?</p> <p>9 A No, I haven't.</p> <p>10 Q Do you know what conflicts of interest, if any, the</p> <p>11 authors may have?</p> <p>12 MS. PARFITT: Objection; form.</p> <p>13 THE WITNESS: No, I don't.</p> <p>14 Q (By Mr. Williams) Do you know whether some of the</p> <p>15 authors are serving as consultants to the plaintiffs in</p> <p>16 this litigation?</p> <p>17 A No, I don't.</p> <p>18 Q Were you asked to be a co-author of that paper?</p> <p>19 A No, I wasn't.</p> <p>20 Q Did you provide comments to it?</p> <p>21 A No, I didn't.</p> <p>22 Q Did the authors ever consult you in any way in connection</p> <p>23 with their publication?</p> <p>24 A No, they didn't.</p> <p>25 Q Did you attend the National Cancer Institute directors'</p>

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<p>1 meeting in Lyon, France on July 11, 2013 of last year,</p> <p>2 2018?</p> <p>3 A No, I didn't.</p> <p>4 Q The Taher study contains a meta-analysis, right?</p> <p>5 A That's correct.</p> <p>6 Q If you turn to Page 28, Page 28 calculates or reports an</p> <p>7 overall relative risk of 1.28 with a confidence interval</p> <p>8 of 1.20 to 1.37, right?</p> <p>9 A It's written there-- okay, yes.</p> <p>10 Q If you turn to Page 49, under the heading, "Conclusion,"</p> <p>11 the very last sentence says, in part, "The present</p> <p>12 comprehensive evaluation of all currently available</p> <p>13 relevant data indicates that perineal exposure to talc</p> <p>14 powder is a possible cause of ovarian cancer in humans,"</p> <p>15 right?</p> <p>16 A Yes, I see that.</p> <p>17 Q Do you agree that the 2018 paper represents a</p> <p>18 comprehensive evaluation of all currently available</p> <p>19 relative data?</p> <p>20 A It appeared to be a relevant meta-analysis.</p> <p>21 As you mentioned, it's not peer-reviewed.</p> <p>22 I would like to see it be peer-reviewed, but it has</p> <p>23 a remarkably similar relative risk of the other</p> <p>24 meta-analyses that I've reviewed that were peer-reviewed,</p> <p>25 so not only the most recent comprehensive ones but also</p>	<p>1 International Association for Research of Cancer, 2010</p> <p>2 monograph with respect to perineal use of talc, right?</p> <p>3 MS. PARFITT: Objection; form.</p> <p>4 THE WITNESS: 2010 monograph was from</p> <p>5 data up until 2007, so they did not have the benefit of</p> <p>6 the last ten years.</p> <p>7 I believe IARC would have given a stronger</p> <p>8 characterization of talcum powder applied to the perineum</p> <p>9 if they were to review the data today, but they did</p> <p>10 categorize talcum applied to the perineum as a possible</p> <p>11 carcinogen Grade 2B.</p> <p>12 Q (By Mr. Williams) I would move to strike that as</p> <p>13 nonresponsive, Doctor, but my question is:</p> <p>14 You are speculating when you say what IARC would or</p> <p>15 would not have done; are you not?</p> <p>16 MS. PARFITT: Objection--</p> <p>17 THE WITNESS: Correct.</p> <p>18 Q (By Mr. Williams) In fact, and point of fact, in 2010</p> <p>19 IARC, in the 2010 monograph, reached a conclusion that</p> <p>20 perineal exposure to talcum powder is a possible cause of</p> <p>21 ovarian cancer, and they put it in Group 2B, right?</p> <p>22 MS. PARFITT: Objection; form.</p> <p>23 THE WITNESS: Using data that they had</p> <p>24 available and through 2007, then yes, they classified it</p> <p>25 that way in 2B.</p>
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<p>1 the previous meta-analyses.</p> <p>2 Q Do you agree with the conclusion of the authors in Taher</p> <p>3 2018 that perineal exposure to talcum powder is a</p> <p>4 possible cause of ovarian cancer in humans?</p> <p>5 A I believe that it is a cause of ovarian cancer in humans.</p> <p>6 Q My question is different.</p> <p>7 My question is whether you agree with the conclusion</p> <p>8 of the authors, what they wrote here, which is that</p> <p>9 perineal exposure to talcum powder is a possible cause of</p> <p>10 ovarian cancer in humans.</p> <p>11 A And I am saying I would use a stronger statement than</p> <p>12 that.</p> <p>13 I would say these data support a causal association</p> <p>14 with cancer, ovarian cancer.</p> <p>15 Q So you disagree with them?</p> <p>16 A Yes.</p> <p>17 Q It would be faster if you just do that upfront.</p> <p>18 A I like to be exact. Sorry.</p> <p>19 Q Just so we're clear, you disagree with the conclusion of</p> <p>20 the authors in the Taher study, that talcum powder is a</p> <p>21 possible cause of ovarian cancer in humans, right?</p> <p>22 A I believe that talcum powder product use is the cause of</p> <p>23 ovarian cancer in humans, based on my review.</p> <p>24 Q The conclusion in this Taher 2018 article is the same as</p> <p>25 that-- as the conclusion that was reached in the IARC,</p>	<p>1 Q (By Mr. Williams) Do you have any criticisms of the</p> <p>2 Taher 2018 meta-analysis?</p> <p>3 A As I mentioned before, it has remarkable similar results</p> <p>4 to the other meta-analyses, so that gave me some</p> <p>5 confidence.</p> <p>6 I was a little curious why they picked-- I think</p> <p>7 it's some of the supplementary tables.</p> <p>8 They picked relative risk for some of the-- a couple</p> <p>9 of the studies that I would not have picked, and some of</p> <p>10 the meta-analyses did not pick-- when many of the studies</p> <p>11 have presented data, it's a little difficult to tell</p> <p>12 which of the data are the most basic, meaning no use of</p> <p>13 talcum powder products to the perineum versus any use,</p> <p>14 and sometimes it's difficult to determine which is the</p> <p>15 correct relative risk to pick, odds ratio, but I don't</p> <p>16 have that here, don't have the supplemental data here.</p> <p>17 Q Other than what you've just expressed, do you have any</p> <p>18 other criticisms?</p> <p>19 A I didn't see other concerns.</p> <p>20 I think Table No. 2, the summary for the Bradford</p> <p>21 Hill criteria of causation, they--</p> <p>22 Q Could you give me the page?</p> <p>23 A I'm sorry, Page 25, Table No. 2.</p> <p>24 Q Thank you.</p> <p>25 A The question I had there is when they looked at strengths</p>

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<p>1 of association, they looked across individual studies and</p> <p>2 didn't take into account the meta-analyses, so I think</p> <p>3 they could have used their own data as well as the other</p> <p>4 meta-analyses, and they could have mentioned that there</p> <p>5 as part of strengths of association.</p> <p>6 Q Have you now listed all of your criticisms of the study?</p> <p>7 A Yes, I believe so.</p> <p>8 Q Do you believe it was improper of the authors of this</p> <p>9 study to include both the Wu 2009 and the Wu 2015 studies</p> <p>10 in the meta-analysis, as reflected on Page 29?</p> <p>11 A I would have to look back and see if those are the same--</p> <p>12 if they include some of the same cases.</p> <p>13 Q If they included the same cases, then for the reasons you</p> <p>14 described earlier today, you would criticize this study</p> <p>15 because there would be double counting, right?</p> <p>16 MS. PARFITT: Objection.</p> <p>17 THE WITNESS: Yes.</p> <p>18 Q (By Mr. Williams) Please turn to Page 3 on-- Figure</p> <p>19 No. 3 on Page 39.</p> <p>20 It says, underneath that table, "Figure No. 3:</p> <p>21 Ovarian cancer risk estimates at increasing levels of</p> <p>22 exposure to talc, as reported from multiple studies."</p> <p>23 Do you see that?</p> <p>24 A Yes.</p> <p>25 Q Does Figure No. 3 provide evidence of a dose-response</p>	<p>1 THE WITNESS: That's what they stated,</p> <p>2 yes.</p> <p>3 Q (By Mr. Williams) And the importance of statistical</p> <p>4 significance is-- strike that.</p> <p>5 Statistical significance is evaluated in order for</p> <p>6 epidemiologists and other researchers to try to rule out</p> <p>7 chance, right?</p> <p>8 A Statistical significance depends largely on sample size,</p> <p>9 and it's merely a probability, so if you have a P value</p> <p>10 of 0.05, it means you have a five percent chance of</p> <p>11 making an error.</p> <p>12 There's nothing magical about 0.05.</p> <p>13 0.06 could be a very relevant study as well.</p> <p>14 Statistical significance is often determined-- it's</p> <p>15 often thought to be statistically significant if the P</p> <p>16 value is less than or equal to 0.05.</p> <p>17 As I said, it's not magical.</p> <p>18 It really depends on sample size, so when I look at</p> <p>19 studies, I look at the totality of evidence, I look at</p> <p>20 consistency, and I look at whether the relative risk is</p> <p>21 above one consistently.</p> <p>22 Q What I'm trying to get at, Doctor, is whether-- is the</p> <p>23 purpose of statistical significance.</p> <p>24 Will you agree with me, and you can say "no," you</p> <p>25 can say "yes," you can say "maybe," but do you agree with</p>
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<p>1 relationship, in your opinion?</p> <p>2 A I don't think I could evaluate that because I don't see</p> <p>3 an explanation of where they get that data from.</p> <p>4 Q Let me ask you to look back on-- at Page 29-- actually,</p> <p>5 Page 25. Excuse me.</p> <p>6 Do you see where it says, "Consistency: 15 out of</p> <p>7 30 studies reported positive and significant associations</p> <p>8 reported in:" and then there's a colon and four bullet</p> <p>9 points?</p> <p>10 Do you see that?</p> <p>11 A Yes.</p> <p>12 Q 15 out of 30 is 50 percent of the case-control studies,</p> <p>13 right-- 15 out of 30 is 50 percent of the total number of</p> <p>14 studies reported, right?</p> <p>15 MS. PARFITT: Objection; form.</p> <p>16 THE WITNESS: Yes, that would be 50</p> <p>17 percent.</p> <p>18 Q (By Mr. Williams) And 50 percent of the studies did not</p> <p>19 find a positive significant association that was</p> <p>20 statistically significant, correct?</p> <p>21 MS. PARFITT: Objection; form,</p> <p>22 misstates the data.</p> <p>23 THE WITNESS: You are asking me if</p> <p>24 that's what it stated?</p> <p>25 MR. WILLIAMS: Yes.</p>	<p>1 me or not that the purpose of evaluating statistical</p> <p>2 significance is to try to rule out the possibility that</p> <p>3 results are a result of chance?</p> <p>4 A I would modify that.</p> <p>5 I would say you would look at a statistical test in</p> <p>6 order to determine what is the likelihood that chance</p> <p>7 explained your result.</p> <p>8 I wouldn't say the word "rule out," because, as I</p> <p>9 mentioned, a P value of 0.06 could be as relevant as a P</p> <p>10 value of 0.05.</p> <p>11 It really depends on the sample size.</p> <p>12 Q You are familiar with IARC ratings?</p> <p>13 You mentioned them earlier today, right?</p> <p>14 A Yes.</p> <p>15 Q And you know that IARC ratings for Group 2B, which is</p> <p>16 what IARC found for talc in 2006, I think, was that talc</p> <p>17 should be listed as a possible cause of ovarian cancer,</p> <p>18 correct?</p> <p>19 MS. PARFITT: Objection; misstates the</p> <p>20 document.</p> <p>21 THE WITNESS: Maybe I should reframe</p> <p>22 my answer.</p> <p>23 My understanding is a classification 2B means a</p> <p>24 possible carcinogen.</p> <p>25 Q (By Mr. Williams) Okay. And as you sit there, can you</p>

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<p>1 tell us what the definition of a Group 2B substance is, 2 according to IARC? 3 A I don't have that memorized. 4 I do know that there are different panels set up for 5 each carcinogen, and there is an overall group that helps 6 the scientists to decide what classification to put 7 something in, but that-- it's not a clear-cut, 8 necessarily. 9 The scientific panel has to look at the totality of 10 evidence as they decide what level of evidence they have. 11 Q Does it sound familiar to you that in assigning a Group 12 2B status for talcum powder, that the IARC team concluded 13 that chance, bias, and confounding factors could not be 14 ruled out? 15 A I don't have the document in front of me. 16 I would need to look at that. 17 Do we have it? 18 Q We do, and I will get to it in a minute. 19 I am asking you, as you sit here, do you have any 20 memory that the way that IARC analyzes whether a 21 substance is in Group 2B or some other grouping, is that 22 if chance, bias, and confounding factors cannot be ruled 23 out, then the substance should be in Group 2B? 24 MS. PARFITT: Objection; form. 25 Again, object to the memory aspect of this.</p>	<p>1 Q There you refer to sample size as opposed to the number 2 of cases, did you not, in that sentence that I just read 3 you? 4 A The reason I'm hesitating is I do two sample size 5 calculations. 6 In here I am talking about calculation-- I was 7 talking about the sample sizes from case-control studies, 8 and after this link that I provide, the calculation 9 showed the minimum number of cases in controls need to be 10 931 each, and then there's another place where I 11 calculate the cohort sizes. 12 Q Can we stay here for just one moment on Page 48? 13 A Yes. 14 Q First of all, you performed what is known as a power 15 calculation to determine the sample size that you 16 believed is required for a study? 17 A That's correct. 18 Q And you place particular importance, you told me a moment 19 ago, on the number of cancer cases total, correct? 20 A That's correct. 21 Q Based on your calculation, you concluded that the minimum 22 number of cases would need to be 931, correct? 23 A That's correct, to have-- to have good power to detect 24 relative risk of 1.3 with statistical significance of 25 0.05.</p>
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<p>1 If there's a document available, you should show it 2 to her. 3 THE WITNESS: And I can't remember. 4 Q (By Mr. Williams) One reason that you have stated for 5 the lack of statistical significance in cohort studies is 6 the sample size in those studies, correct? 7 A The number of cases, the sample size of cases, yes. 8 Q Right. 9 So now in your last answer, you are distinguishing 10 between the total sample size on the one hand and the 11 number of cases of cancer on the other, correct? 12 A Yes. 13 Q What's important for your analysis, in terms of sample 14 size, is the number of cancer cases? 15 A That's correct. 16 Q You believe that the number of cases affects the 17 statistical power of the studies? 18 A Yes. 19 Q Doctor, let me ask you about your report though. 20 If you could look at Exhibit No. 2, Page 48, do you 21 see there in the middle of the page it says, "I interpret 22 the lack of statistical significance in some source 23 studies as being due to the small sample sizes of many of 24 these studies"? 25 A Yes.</p>	<p>1 Q You also concluded that the minimum number of controls 2 would need to be 931, correct? 3 A That's the simplest model. 4 Different case-control studies will have different 5 numbers, and that can affect the power one way or the 6 other. 7 I just did a simple calculation, but you could have 8 power increased by having a small number more of controls 9 or a small number of more cases, so it depends on how-- 10 how it ends up working out, but this is the simplest 11 model. 12 Q The point you were making in performing your power 13 calculation was that meta-analyses, with their larger 14 combined sample sizes, can be used to overcome that lack 15 of statistical power; is that true? 16 A Yes. 17 Q One of the two meta-analyses that you called excellent 18 combine data from three of the cohort studies to arrive 19 at a single risk estimate. 20 Do you remember that? 21 A No, I don't. 22 Which study? 23 Q Let me ask you to look at the 2017 Berge analysis, and 24 let's use Exhibit No. 16A. 25 MS. PARFITT: Not cutting you off</p>

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<p style="text-align: right;">Page 218</p> <p>1 right now, but maybe when you get to a good place, we can 2 take a break.</p> <p>3 MR. WILLIAMS: Okay. Sure.</p> <p>4 Q (By Mr. Williams) Do you have Exhibit No. 16A in front 5 of you?</p> <p>6 A I do.</p> <p>7 Q And I would like to have you focus on Page-- I believe 8 it's 7, Figure No. 2.</p> <p>9 Do you see where the authors list the three cohort 10 studies they analyzed?</p> <p>11 A Yes.</p> <p>12 Q Gates 2010, Houghton 2014, Gonzalez 2016?</p> <p>13 A Hold on a minute.</p> <p>14 Q And "Houghton" is--</p> <p>15 A Sorry.</p> <p>16 (Phone interruption) I was getting a call on this. 17 I am going to turn it off.</p> <p>18 Q Do you see in the middle of Page 7 the reference to 19 Gates, Houghton, and Gonzalez?</p> <p>20 Do you see the reference in Figure No. 2, middle of 21 the page, that says, "Cohort studies," and it references 22 those three studies?</p> <p>23 A Yes.</p> <p>24 Q And "Houghton," for the record, is H-O-U-G-H-T-O-N. 25 Now, look back one page to Page 6 of Exhibit</p>	<p style="text-align: right;">Page 220</p> <p>1 Q If you add those two numbers together, what do you get?</p> <p>2 A I don't know exactly-- over 1300.</p> <p>3 Q 1300 is more than 931, correct?</p> <p>4 A Yes.</p> <p>5 Q 900 and 1300-- to be precise, it's 1372. You add those 6 two numbers together.</p> <p>7 1372 cancer cases is well above the 931 that you 8 calculated would be necessary to find statistical 9 significance, right?</p> <p>10 A Yes.</p> <p>11 Q And because of the nature of cohort studies, there were 12 also many times that the number of women who did not get 13 ovarian cancer-- right-- that's a separate number?</p> <p>14 A What did you say about the cohort studies?</p> <p>15 Q In addition to the cases where women ultimately, 16 unfortunately, were diagnosed with cancer, the 1372, 17 there are many times that number of women who were 18 followed along in their lives who did not get ovarian 19 cancer, correct?</p> <p>20 A Yes.</p> <p>21 Q So this meta-analysis is sufficient, under your power 22 calculation, to be able to find a statistically 23 significant association, true?</p> <p>24 A Yes, and that's why overall we see 1.22 is statistically 25 significant.</p>
<p style="text-align: right;">Page 219</p> <p>1 No. 16A, and take a look at the paragraph starting at the 2 top of the right column.</p> <p>3 Do you see that one?</p> <p>4 A Yes.</p> <p>5 Q About halfway down that paragraph the authors state as 6 follows, "It should be noted that the cohort studies 7 included in the meta-analysis comprised a total of 429 8 cases of ovarian cases exposed to genital talc and 943 9 unexposed cases: the statistical power of the 10 meta-analysis of these cohort studies to detect a risk 11 ratio of 1.25, similar to the result of the meta-analysis 12 of case-control studies, was 0.99. Thus, low power of 13 cohort studies cannot be invoked as explanation of the 14 heterogeneity of results."</p> <p>15 Did I read that correctly?</p> <p>16 A Yes, you did.</p> <p>17 Q Now, they reference here in the Berge study-- strike 18 that. Let me start over.</p> <p>19 The Berge study is one of the two meta-analyses that 20 you said is an excellent study, correct?</p> <p>21 A Yes.</p> <p>22 Q And what they list here on Page No. 6 is 429 cases of 23 ovarian cancer and 943 unexposed cases.</p> <p>24 Is that correct?</p> <p>25 A Yes.</p>	<p style="text-align: right;">Page 221</p> <p>1 Q Please explain.</p> <p>2 A Pardon?</p> <p>3 Q Please explain your answer.</p> <p>4 A The overall relative risk of 1.22, the confidence 5 interval is 1.13 to 1.3-- you see the overall 6 statistically significant effect.</p> <p>7 Q That wasn't what they concluded for the cohort studies 8 though, correct?</p> <p>9 The cohort studies had the following on page-- I am 10 looking at Page 7, Figure No. 2.</p> <p>11 The cohort studies, for Gates it was 1.12, for 12 Gonzalez it was 0.73-- excuse me, I misspoke.</p> <p>13 For Gates it was 1.06, for Houghton it was 1.12, and 14 for Gonzalez the relative risk was 0.73, correct?</p> <p>15 A 0.73, yes.</p> <p>16 Q So if you look at the cohort studies, separate and apart 17 from the case-control studies that are listed above, we 18 can agree that the relative risk is nowhere near 1.22?</p> <p>19 MS. PARFITT: Objection; form.</p> <p>20 Q (By Mr. Williams) Right?</p> <p>21 MS. PARFITT: Objection; form.</p> <p>22 THE WITNESS: Yeah, I think the-- the 23 way I look at the meta-analysis, is I look at all of the 24 studies together.</p> <p>25 I don't just look at one particular type separate</p>

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<p style="text-align: right;">Page 222</p> <p>1 from others, but as an example, the Houghton study, which 2 had about 400 cases, I believe, the Women's Health 3 Initiative, with a relative risk of 1.12, if they had had 4 900 cases, that probably would have been a statistically 5 significant result, so that's what the power calculation 6 does. 7 In this case you have the Gonzalez-- the sister 8 study is what brings the relative risk down closer to one 9 because you do have one negative result there, but 10 overall, looking at all of the meta-analyses-- all of the 11 studies together, you see definitely a trend towards a 12 relative risk consistently above one. 13 Q (By Mr. Williams) Now-- have you completed your answer? 14 A Yes. 15 Q You just mentioned a moment ago that with a relative risk 16 of 1.12, if they had 900 cases, they probably would have 17 been a statistically significant-- that probably would 18 have been a statistically significant result. 19 When you say that that probably would have been the 20 case in the women's health study, you're speculating 21 there, aren't you? 22 MS. PARFITT: Objection; form. 23 THE WITNESS: I am speculating from my 24 previous experience with working with the Women's Health 25 Initiative, that with very large numbers of cases if you</p>	<p style="text-align: right;">Page 224</p> <p>1 that was available at the time, and in total that's what 2 I look at. 3 The issue with the cohort studies are that the 4 information on talcum powder product use was collected at 5 one point in time. It was never updated, and it was not 6 retrospective, so we don't know what-- lifetime use in 7 those cohort studies. 8 Q (By Mr. Williams) We'll take a break in a moment, but my 9 question before the break is this: 10 I was asking, for purposes of my question, for you 11 to exclude case-control studies from your analysis. 12 My question was: 13 If you were doing an analysis that had been based on 14 the cohort studies, and not on your analysis of the 15 case-control study relative risks, you would not have 16 been able to conclude that perineal use of talc causes 17 ovarian cancer with a 1.02 relative risk that is not 18 statistically significant, right? 19 MS. PARFITT: Objection; form, 20 misstates her testimony and her opinions. 21 THE WITNESS: I think that's 22 speculative because I wouldn't have ignored the 23 significant amount of data from case-control studies. 24 Q (By Mr. Williams) On the question of whether or not the 25 difference between case-control and cohort studies may be</p>
<p style="text-align: right;">Page 223</p> <p>1 have-- even with small relative risk you will have a 2 statistically significant result, an amount, that you 3 would correct on speculating what would be seen with this 4 particular data set. 5 Q (By Mr. Williams) Let me ask you to focus on Page 7 of 6 the exhibit and Figure No. 2, again, and the cohort 7 studies for Exhibit No. 16A, the Berge study. 8 You see there's a subtotal there for the cohort 9 studies at the bottom of the table, right? 10 A Yes. 11 Q The combined relative risk for the cohort studies is 12 1.02, no statistical significance, correct? 13 A Correct. 14 Q The confidence interval combined for those was 0.85 to 15 1.20, correct? 16 A Correct. 17 Q If you had been basing your analysis on the cohort 18 studies and not on an analysis of the case-control 19 studies, you would not have been able to reach your 20 conclusion that use of talc is a cause of ovarian cancer, 21 true? 22 MS. PARFITT: Objection; form, 23 misstates the evidence. 24 THE WITNESS: I looked at the totality 25 of evidence and looked at all of the epidemiologic data</p>	<p style="text-align: right;">Page 225</p> <p>1 due to sample size and resulting low power, you come to 2 the opposite conclusion as the authors of the Berge 2017 3 study that you are relying upon, correct? 4 MS. PARFITT: Objection; form, 5 misstates her testimony. 6 THE WITNESS: I am not sure why you 7 come to that. 8 I have the opposite conclusion. 9 Q (By Mr. Williams) Well, the authors of the Berge study 10 concluded that-- the authors of the Berge study concluded 11 that low power of cohort studies cannot be invoked as an 12 explanation of the heterogeneity of results, right? 13 That's what they wrote? 14 A That's what they wrote. 15 Q On the question of whether or not the difference between 16 case-control and cohort studies may be due to sample size 17 and resulting low power, you come to the opposite 18 conclusion as the authors of the Berge study, correct? 19 MS. PARFITT: Objection; form. 20 THE WITNESS: I don't remember coming 21 to the opposite conclusion. 22 I have opposite-- I have alternative reason why I 23 think the cohort studies could have lower relative risk 24 than the case-control studies, and-- which I've just 25 stated about the way the exposures are collected.</p>

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<p>1 Q (By Mr. Williams) In your report, Dr. McTiernan, you</p> <p>2 dealt with the heterogeneity issue between the relative</p> <p>3 risk findings for case-controls versus the relative risk</p> <p>4 findings for cohorts.</p> <p>5 You dealt with that disparity by doing a power</p> <p>6 calculation and concluding that you needed 931 cases in</p> <p>7 order to have sufficient power.</p> <p>8 That's what you said, right?</p> <p>9 A A study-- I was talking about individual studies.</p> <p>10 I wasn't talking about the combined group of cohort</p> <p>11 studies.</p> <p>12 Q What the authors said on Page 6 of Exhibit No. 16A was,</p> <p>13 "Thus, low power of cohort studies cannot be invoked as</p> <p>14 an explanation of the heterogeneity of results."</p> <p>15 They said that, right?</p> <p>16 A Yes, and I think they mean the cohort studies combined.</p> <p>17 Q I'm sorry?</p> <p>18 A They're talking about the cohort studies combined.</p> <p>19 I'm talking about individual studies.</p> <p>20 Q And you disagree with that conclusion, true or not true?</p> <p>21 MS. PARFITT: Objection; form.</p> <p>22 THE WITNESS: I think that they're</p> <p>23 correct in what they're saying, that they had sufficient</p> <p>24 power to find a relative risk if it was there, if the</p> <p>25 study was done directly when they added those three</p>	<p>1 MS. PARFITT: Objection; form.</p> <p>2 THE WITNESS: You are talking about</p> <p>3 this-- yes.</p> <p>4 Q (By Mr. Williams) In your last answer or two answers</p> <p>5 ago, you referenced the fact that two of the cohort</p> <p>6 studies had relative risks above one.</p> <p>7 Do you remember saying that?</p> <p>8 A Yes.</p> <p>9 Q You are referring to Gates, which was 1.06, and Houghton,</p> <p>10 which is 1.12, correct?</p> <p>11 A Correct.</p> <p>12 Q The other relative risk was 0.73, correct?</p> <p>13 A Correct.</p> <p>14 Q If it had been statistically significant, that would show</p> <p>15 a protective effect from the use of talc, correct?</p> <p>16 MS. PARFITT: Objection; form.</p> <p>17 THE WITNESS: Correct.</p> <p>18 Q (By Mr. Williams) Do you think that relative risks of</p> <p>19 1.06 and 1.12 are weak? strong? moderate?</p> <p>20 How would you characterize those numbers?</p> <p>21 MS. PARFITT: Objection; form.</p> <p>22 THE WITNESS: I tend to look at the</p> <p>23 number of what they are, rather than giving an adjective</p> <p>24 to it.</p> <p>25 I believe one possibility for these cohort studies</p>
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<p>1 studies together, but I'm saying there were alternative</p> <p>2 reasons why the relative risk is lower, so there's two</p> <p>3 issues, the relative risk and the power and statistical</p> <p>4 significance, and the relative risk for two of those</p> <p>5 studies is over one.</p> <p>6 They used Gates-- Gertig had a little bit different</p> <p>7 level, but the data was collected in very different ways</p> <p>8 for cohort studies than case-control studies.</p> <p>9 Another problem with the cohort studies is that they</p> <p>10 did not follow the women for very long, on average, which</p> <p>11 was the case of 12 studies that have lifetime exposure,</p> <p>12 so the cohort studies may have not had all of the cases</p> <p>13 develop that were going to be developed, so there are</p> <p>14 reasons-- but it's two different reasons: the effect</p> <p>15 size, which is the relative risk, and the statistical</p> <p>16 significance, which is the P value or the confidence</p> <p>17 intervals.</p> <p>18 Q (By Mr. Williams) With respect to the issue of power,</p> <p>19 you said you needed to get to 931 cases, right?</p> <p>20 MS. PARFITT: Objection; form.</p> <p>21 THE WITNESS: I calculated 91-- 931</p> <p>22 for an individual study.</p> <p>23 Q (By Mr. Williams) And in these cases, if you combine the</p> <p>24 cohort studies, the total number of cases, they are far</p> <p>25 in excess of that number, right?</p>	<p>1 to have lower relative risk is because of the less</p> <p>2 accuracy in collecting the exposure.</p> <p>3 It tends to reduce the point estimate, which is the</p> <p>4 relative risk, if the exposure data is not collected with</p> <p>5 as much refinement as you can see in-- as we've seen in</p> <p>6 some of the other studies.</p> <p>7 Q (By Mr. Williams) Why would it reduce the number rather</p> <p>8 than raise the number?</p> <p>9 Couldn't it do either?</p> <p>10 A I am not sure exactly why, but it tends to do that-- by</p> <p>11 having incomplete information about an exposure, it tends</p> <p>12 to lower the relative risk.</p> <p>13 Q Can you point us to any treatise, any study, any analysis</p> <p>14 that makes that point?</p> <p>15 A Yes.</p> <p>16 Q That you just made?</p> <p>17 A Yes.</p> <p>18 Q Go ahead.</p> <p>19 A I have a reference.</p> <p>20 Q And then I promise we'll take a break.</p> <p>21 A Flegal, Brownie, and Haas, so Reference No. 45--</p> <p>22 Q And you are referring to Reference No. 45 from your</p> <p>23 report?</p> <p>24 A Yes, Reference No. 45.</p> <p>25 MS. PARFITT: Counsel, with your</p>

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<p>1 permission, I will hand her my--</p> <p>2 MR. WILLIAMS: Please.</p> <p>3 Q (By Mr. Williams) For the record, are you looking,</p> <p>4 Dr. McTiernan, to the portion of the Flegal, F-L-E-G-A-L,</p> <p>5 study, Item No. 45 on your reference list, to try to find</p> <p>6 something that supports your conclusion that a lack of--</p> <p>7 I can't remember how you put it, but a lack of sufficient</p> <p>8 questions in a cohort study leads to a lower risk ratio?</p> <p>9 A So I'll read from the abstract, the first two sentences,</p> <p>10 "In epidemiologic studies individuals may be</p> <p>11 misclassified with respect to exposure to a risk factor</p> <p>12 for disease.</p> <p>13 "Such misclassification causes the relative risk of</p> <p>14 disease associated with exposure in the population to be</p> <p>15 biased toward the null value."</p> <p>16 Q And what is it that you believe caused people-- strike</p> <p>17 that.</p> <p>18 I take it you conclude here that the cohort studies</p> <p>19 somehow misclassified some of the women who were</p> <p>20 participating in the study?</p> <p>21 A In the Nurses' Health Study women were asked in 1982, at</p> <p>22 one point, whether they used these products, and it was</p> <p>23 never updated, and it did not ask about their lifetime</p> <p>24 use before that.</p> <p>25 The Women's Health Initiative asked if they had ever</p>	<p>1 At the bottom of Page 28, the last sentence that</p> <p>2 carries over, you wrote, "It should be noted that ovarian</p> <p>3 talc particle burden may not be influenced by number of</p> <p>4 applications of perineal talc usage, and therefore the</p> <p>5 typical dose response relationship may not be necessary</p> <p>6 for establishing causality between perineal talcum powder</p> <p>7 product use and the risk for ovarian cancer."</p> <p>8 What's the basis for that statement?</p> <p>9 A I think I addressed that a little bit this morning, that</p> <p>10 if a woman is exposed to perineal talc and it moves up to</p> <p>11 the fallopian tube or ovarian area, all she would need is</p> <p>12 potentially one dose to then set up inflammation.</p> <p>13 The more that she's exposed to, that suggests the</p> <p>14 more likelihood of having the talc move up to that area,</p> <p>15 so we do look at dose responses to help support this</p> <p>16 association, but it still seems possible that a smaller</p> <p>17 number of doses could still increase risk.</p> <p>18 The reference that I used here, 64, Heller, do we</p> <p>19 have that available?</p> <p>20 (Exhibit No. 18 marked</p> <p>21 for identification.)</p> <p>22</p> <p>23 Q (By Mr. Williams) And we will mark the Heller study as</p> <p>24 Exhibit No. 18.</p> <p>25 If you could, just point me to the page that you're</p>
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<p>1 used it when they entered the study, so that was between</p> <p>2 1992 and 1996.</p> <p>3 It was not updated either.</p> <p>4 It didn't have a full lifetime exposure collected,</p> <p>5 so really you only have one point in time for those two.</p> <p>6 One of them-- one of them asked about years of use</p> <p>7 and one asked about frequency, but neither asked about</p> <p>8 both.</p> <p>9 This is a typical underestimate of exposure when</p> <p>10 you're asking people just at one point in time and not</p> <p>11 updating and not going back in time.</p> <p>12 Q Anything else you want to add?</p> <p>13 A No.</p> <p>14 MR. WILLIAMS: Let's take a break.</p> <p>15 VIDEOGRAPHER: Going off the record,</p> <p>16 the time is 3:19 p.m.</p> <p>17 (Recess 3:19 to 3:39 p.m.)</p> <p>18</p> <p>19 VIDEOGRAPHER: We are back on the</p> <p>20 record. This is the start of Media 4. The time is 3:39</p> <p>21 p.m.</p> <p>22 Q (By Mr. Williams) Dr. McTiernan, do you have Exhibit</p> <p>23 No. 2 in front of you, your report?</p> <p>24 A Yes.</p> <p>25 Q Could you turn to Page 28.</p>	<p>1 referring to.</p> <p>2 A So, yes, if you look at-- just looking at Table No. 1,</p> <p>3 this is 12 women who reported talc use.</p> <p>4 You can see the talc counts weren't necessarily</p> <p>5 correlated with the lifetime talc applications, and this</p> <p>6 is estimated by a woman's report.</p> <p>7 So even women that have a smaller number of</p> <p>8 applications could have a very high talc count.</p> <p>9 Q Have you finished your answer?</p> <p>10 A Yes.</p> <p>11 Q Couldn't that very high talc count be as a result of the</p> <p>12 fact that talc is all over the environment, not just from</p> <p>13 talcum powder but from things we eat, places we go,</p> <p>14 contamination?</p> <p>15 Couldn't it be explained by that?</p> <p>16 MS. PARFITT: Objection; form.</p> <p>17 THE WITNESS: It seems like a likely</p> <p>18 way for talc to be present in the ovaries is through</p> <p>19 movement up through the genital tract.</p> <p>20 There is some data suggesting that, yes, talc could</p> <p>21 migrate through the lymph system, but there's much more</p> <p>22 data showing that particles can move-- inert particles</p> <p>23 can move through the genital tract up through the</p> <p>24 fallopian tubes and to the ovaries in both animals and</p> <p>25 humans.</p>

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<p>1 Q (By Mr. Williams) Do you remember that the Heller study</p> <p>2 looked at groups of women that both used talcum powder in</p> <p>3 the perineal area and women who did not?</p> <p>4 A Yes. It was about half and half, and--</p> <p>5 Q Hold on. Let me ask the question.</p> <p>6 A Sorry.</p> <p>7 Q You do remember that it looked at both groups of women,</p> <p>8 those who used talc and those who did not, correct?</p> <p>9 A Yes.</p> <p>10 Q And then it looked at their ovaries to determine which</p> <p>11 ones had any evidence of talcum powder.</p> <p>12 Do you remember that?</p> <p>13 A Yes.</p> <p>14 Q And do you remember that the Heller study concluded that</p> <p>15 there were more women who had talcum powder in their</p> <p>16 ovaries who had never used talcum powder in the perineal</p> <p>17 area than there were women who had talc in their ovaries</p> <p>18 who had reported use of talcum powder in the perineal</p> <p>19 area?</p> <p>20 Do you recall that?</p> <p>21 MS. PARFITT: Objection.</p> <p>22 THE WITNESS: What I see in the table</p> <p>23 is a one point different, five versus six.</p> <p>24 They were able then to contact the mothers of these</p> <p>25 women to find out whether the women had been exposed as</p>	<p>1 their genital area that she didn't record, she didn't</p> <p>2 recall.</p> <p>3 Q You're speculating now, aren't you?</p> <p>4 MS. PARFITT: Objection.</p> <p>5 Q (By Mr. Williams) Are you not speculating right now?</p> <p>6 A I don't know. They don't have data saying that the woman</p> <p>7 misrepresented.</p> <p>8 Q What we do have data on is the ages of the women who had</p> <p>9 talc in their ovaries, correct?</p> <p>10 A Yes.</p> <p>11 Q And who were part of this study, right?</p> <p>12 A Yes.</p> <p>13 Q The notion that the fact that they were diapered as</p> <p>14 babies with talcum powder could be an explanation for how</p> <p>15 they had talc in their ovaries doesn't hold up, does it,</p> <p>16 if the ages of the women are, with two exceptions, people</p> <p>17 who are in their 60s and 50s and 40s, right?</p> <p>18 MS. PARFITT: Objection; form,</p> <p>19 misstates the data.</p> <p>20 THE WITNESS: I don't know if we have</p> <p>21 data that can show that, but if talc has migrated up and</p> <p>22 is in the peritoneal area, it sits there. I don't know</p> <p>23 how it would be removed.</p> <p>24 It doesn't seem implausible to me that it could</p> <p>25 remain there for years.</p>
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<p>1 babies, if they had been diapered with talc, and you</p> <p>2 could see quite a few-- three additional that did have</p> <p>3 genital exposure from talc use as babies.</p> <p>4 Q (By Mr. Williams) Dr. McTiernan, what is the latency</p> <p>5 period for ovarian cancer?</p> <p>6 A It's decades, so it's thought to be-- it could be 30, 40</p> <p>7 years.</p> <p>8 Q Isn't it 20 or 30 years?</p> <p>9 MS. PARFITT: Objection; form.</p> <p>10 THE WITNESS: It's not clear if it's</p> <p>11 exactly that, but it could be much longer.</p> <p>12 Q (By Mr. Williams) Well, take a look at the ages of the</p> <p>13 women in Table No. 2.</p> <p>14 Do you see those ages?</p> <p>15 Wouldn't those women have had to have been diapered</p> <p>16 in their 30s and 40s, by your analysis?</p> <p>17 A No, I see one woman is 59, so that would have been a long</p> <p>18 period.</p> <p>19 One is 40.</p> <p>20 One is 64.</p> <p>21 Q If a woman were 59 and the latency period were 40 years,</p> <p>22 that would mean that she would have had to have been</p> <p>23 diapered when she was 19, right?</p> <p>24 A The latency could have been longer in some.</p> <p>25 There's also a possibility of other exposure to</p>	<p>1 Q (By Mr. Williams) Do you have any opinion on how long</p> <p>2 talc particles stay in a woman's ovary, assuming it can</p> <p>3 get to an ovary?</p> <p>4 A I have no data to show me one way or the other.</p> <p>5 Q What we do know from the Heller study though is in Table</p> <p>6 No. 3 for those women who reported talc use, five of the</p> <p>7 12 had talc in their ovary, correct?</p> <p>8 A That's correct.</p> <p>9 Q And six of the women, who reported no talc use, six of</p> <p>10 the 12 had talc in their ovaries, correct?</p> <p>11 A That's correct.</p> <p>12 Q Now, you cited Heller as a basis for-- strike that.</p> <p>13 You criticized the cohort studies earlier today for</p> <p>14 asking only at one point in time whether women used</p> <p>15 talcum powder.</p> <p>16 Do you recall that testimony?</p> <p>17 A Yes, in the sense that it may underreport by asking about</p> <p>18 one period in time.</p> <p>19 Q But you also just testified a few moments ago and you</p> <p>20 testified earlier today that one-time exposure is</p> <p>21 sufficient to support the conclusion that talc causes</p> <p>22 ovarian cancer, right?</p> <p>23 A I don't recall saying that, and I did say that-- I</p> <p>24 thought I just said that the women may not have</p> <p>25 remembered using it.</p>

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<p>1 The ones that said they didn't, they may have not</p> <p>2 remembered, and that is underreporting.</p> <p>3 Q But wouldn't asking the question whether-- one time</p> <p>4 whether a woman ever used talcum powder be enough to give</p> <p>5 the cohort studies the ability to analyze whether there</p> <p>6 was an overall statistically significant association, if</p> <p>7 in fact one existed, given your testimony that all it</p> <p>8 takes is one exposure?</p> <p>9 A I think-- sorry, are you talking about my testimony of</p> <p>10 one exposure in order to cause ovarian cancer?</p> <p>11 Q Yes.</p> <p>12 A There may be other reasons women could say it could not</p> <p>13 report use of talc-- they may not remember it.</p> <p>14 They may not feel comfortable reporting it.</p> <p>15 In these cohort studies there were some subjects</p> <p>16 that were not included because they didn't report use.</p> <p>17 One of the cohort studies didn't include about 500</p> <p>18 women because they didn't have information, they didn't</p> <p>19 answer the question.</p> <p>20 Q You are speculating now, aren't you?</p> <p>21 MS. PARFITT: Objection; form.</p> <p>22 THE WITNESS: We can look at the</p> <p>23 cohort studies to see what the numbers were that didn't</p> <p>24 remember.</p> <p>25 Q (By Mr. Williams) Is it your testimony that use of--</p>	<p>1 THE WITNESS: I would have to look at</p> <p>2 the question again, but they were asked at one point if</p> <p>3 they were using, and--</p> <p>4 Q (By Mr. Williams) Weren't they asked in some of the</p> <p>5 cohort studies whether they ever used talcum powder?</p> <p>6 A One of them did and one didn't, so I would have to look</p> <p>7 back.</p> <p>8 Q Regardless of which one is which, which one said, "Look</p> <p>9 back" or which one side, "Are you currently using," isn't</p> <p>10 the point that if talcum powder use in the perineal area</p> <p>11 is a habitual thing that women did and do after</p> <p>12 showering, after exercising-- after being out in the</p> <p>13 world, if they're hot, if it is something that is</p> <p>14 habitually done, then is there any reason to believe that</p> <p>15 when a woman reports that she has used talcum powder,</p> <p>16 that she's only done it one time?</p> <p>17 MS. PARFITT: Objection; form.</p> <p>18 THE WITNESS: I don't know the answer</p> <p>19 to that. I haven't seen the data.</p> <p>20 Q (By Mr. Williams) Earlier today you were asked questions</p> <p>21 about cohort study methodology, and I believe you said</p> <p>22 that one of the problems with the cohort studies is that</p> <p>23 they ask about a lot of substances and not just talcum</p> <p>24 powder.</p> <p>25 Do you recall saying that?</p>
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<p>1 strike that.</p> <p>2 Do you have an understanding, as you sit there, as</p> <p>3 to whether or not use of talcum powder in the perineal</p> <p>4 area is a habitual activity or something that is done</p> <p>5 once and never again?</p> <p>6 A I don't think we have data showing one way or the other.</p> <p>7 Q Do you believe that there are no studies that talk at all</p> <p>8 about whether or not this is a habit, the use-- and by</p> <p>9 "this," I mean the use of talcum powder in the perineal</p> <p>10 area?</p> <p>11 A I didn't review that.</p> <p>12 The studies talked about what proportion of people</p> <p>13 were using talc at the time that they were interviewed.</p> <p>14 I noticed the Women's Health Initiative is 40</p> <p>15 percent were using it. I think Nurses' Health Study was</p> <p>16 about 50 percent using it, whereas the sister study, a</p> <p>17 very small percent, they were interviewed more recently</p> <p>18 or they answered questions more recently.</p> <p>19 I don't recall the studies determining whether</p> <p>20 somebody had used it once versus several times or a</p> <p>21 habitual use versus nonhabitual use.</p> <p>22 Q So the cohort studies that started in 1982, is it your</p> <p>23 testimony that those women started using talcum powder in</p> <p>24 1982?</p> <p>25 MS. PARFITT: Objection.</p>	<p>1 A Yes.</p> <p>2 Q And isn't it true-- strike that.</p> <p>3 Isn't it true that a number of the cohort studies</p> <p>4 ask about multiple substance-- strike that.</p> <p>5 Isn't it true that a number of the case-control</p> <p>6 studies ask about a number of substances?</p> <p>7 MS. PARFITT: Objection; form.</p> <p>8 THE WITNESS: Without having the</p> <p>9 questionnaires for all of the case-control studies, I</p> <p>10 can't answer about exactly what they asked about other</p> <p>11 variables.</p> <p>12 Certainly case-control studies, many of the ones</p> <p>13 included, asked about several different potential</p> <p>14 exposures in relation to ovarian cancer.</p> <p>15 They were designed to look at ovarian cancer.</p> <p>16 The cohort studies, however, were designed to look</p> <p>17 at exposures related to cardiovascular disease, various</p> <p>18 cancers, osteoporosis, arthritis, cognition, so there are</p> <p>19 many, many different forms that these women filled out,</p> <p>20 and the Women's Health Initiative in the cohort study,</p> <p>21 they were completing forms every year with different</p> <p>22 types of information collected.</p> <p>23 At baseline, which is the only time when talc was</p> <p>24 collected, they had multiple forms that they had to</p> <p>25 complete.</p>

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<p style="text-align: right;">Page 242</p> <p>1 Q (By Mr. Williams) What is it about asking about multiple 2 substances and not just talcum powder that makes that 3 practice in some cohort studies unreliable, in your view? 4 A It could make it unreliable, but it certainly is fatigue, 5 how many questions can somebody answer accurately. 6 The cohort studies were self-administered forms, so 7 the woman had no prompting, no additional help with 8 remembering. 9 The two studies that I could find, the actual 10 questionnaire, the Nurses' Health Study and the Women's 11 Health Initiative, they're very short and simple 12 questions without going through any information about 13 what they might have been doing at different time points 14 in their life. 15 The Nurses' Health Study had one little question 16 about five categories to fill in, so something that's 17 that short can underestimate the level of exposure. 18 Q Does being fatigued make a woman check the box saying 19 that she used talc or does it make her not check the box 20 saying that she used talc? 21 A I don't know. 22 Q Then what does fatigue have to do with it? 23 A If it makes the result less accurate, whichever way it 24 goes, the misclassification, as we just talked about, 25 that then can drive the relative risk lower towards the</p>	<p style="text-align: right;">Page 244</p> <p>1 not all statistically significant, right? 2 MS. PARFITT: Objection; form, 3 misstates her testimony. 4 THE WITNESS: When you look at studies 5 that were small, the smaller, older studies tended to be 6 less likely to have statistical significance, and the 7 newer, larger studies were more likely to be 8 statistically significant. 9 Q (By Mr. Williams) You agree that simply combining data 10 into meta or pooled analyses does not entirely eliminate 11 the underlying flaws of the individual studies, true? 12 A Yes, when you combine data, then the individual study's 13 data still stand. 14 What you're doing by combining data is smoothing out 15 variability across studies and increasing sample size. 16 Q Take a look at the Berge study, 16A, that we were looking 17 at earlier, and take a look at Figure No. 2. 18 That's the Forest plot, right? 19 A Yes. 20 Q This breaks out the case-control and the cohort studies 21 analyzed for the meta-analysis, right? 22 A Yes. 23 Q There's a combined relative risk for the case-controls 24 and the cohort combined, and that is the 1.22 indicated 25 at the bottom of the table, right?</p>
<p style="text-align: right;">Page 243</p> <p>1 null. 2 Q But it also can drive it higher, right, depending on 3 which way it goes? 4 MS. PARFITT: Objection; form. 5 THE WITNESS: Not usually from this 6 classification. It usually drives it towards the null. 7 Q (By Mr. Williams) Your opinion that perineal talc use 8 can cause ovarian cancer is based on what you describe as 9 a statistically significant elevated risk, right? 10 A That's correct, overall, looking at the meta-analysis and 11 the pooled analysis. 12 Q And that statistically significant elevated risk estimate 13 is in combined data in the meta-analysis, correct? 14 A Correct, adding the studies together. 15 Q By combining the data, you are referring to meta-analyses 16 and pooled analyses, right? 17 A Yes. 18 Q Your opinion of that combined data is based upon 19 statistical significance, correct? 20 A Partly. It's based also on consistency across the 21 individual studies and also the effect size consistently 22 being elevated in most of the studies. 23 Q You do agree that when you do not combine the data, 24 meaning when you look at the individual sourced studies 25 from which the meta-analyses are performed, the data is</p>	<p style="text-align: right;">Page 245</p> <p>1 A That's correct. 2 MR. LOCKE: Excuse me, can we just 3 take a quick break? 4 VIDEOGRAPHER: Going off the record, 5 the time is 3:59 p.m. Please stand by. 6 (Recess 3:59 to 4:00 p.m.) 7 8 VIDEOGRAPHER: We are back on the 9 record. The time is 4 p.m. 10 Q (By Mr. Williams) Dr. McTiernan, do you have the Berge 11 study, Exhibit No. 16A, in front of you? 12 A Yes. 13 Q And you are looking at the Forest plot? 14 A Yes. 15 Q I would like to focus you on the case-control studies. 16 I have counted the total number there. 17 I count 24 total. 18 Is that what you count? 19 A Yes. 20 Q If we look at those studies that have a confidence 21 interval that crosses over 1.0, there are 12 of them, 22 correct? 23 A Yes, the earlier studies do. 24 Q And that means that there are 12 that are not 25 statistically significant, correct?</p>

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<p style="text-align: right;">Page 246</p> <p>1 A Yes.</p> <p>2 Q So as between just the case-control studies, the 24</p> <p>3 listed here, at best only 50 percent of them or 12 of</p> <p>4 them reflect a statistically significant association,</p> <p>5 true?</p> <p>6 MS. PARFITT: Objection; form.</p> <p>7 THE WITNESS: And, again, that's</p> <p>8 largely based on sample size.</p> <p>9 The earlier studies tended to be smaller than the</p> <p>10 older ones-- sorry, than the more recent ones, which the</p> <p>11 sample size drives statistical significance.</p> <p>12 Q (By Mr. Williams) It is accurate that 12 of the</p> <p>13 case-control studies did not find a statistically</p> <p>14 significant association, true or not true?</p> <p>15 MS. PARFITT: Objection; form, asked</p> <p>16 and answered.</p> <p>17 THE WITNESS: The sample size drives</p> <p>18 the statistical significance, and the larger, more recent</p> <p>19 studies, were more likely to be statistically</p> <p>20 significant.</p> <p>21 The smaller, older studies, were more likely to be</p> <p>22 not statistically significant.</p> <p>23 Q (By Mr. Williams) The combined risk estimate for the 24</p> <p>24 case-control studies came out to a statistically</p> <p>25 significant number, correct?</p>	<p style="text-align: right;">Page 248</p> <p>1 significant?</p> <p>2 MS. PARFITT: Objection; form, asked</p> <p>3 and answered.</p> <p>4 Q (By Mr. Williams) Am I right?</p> <p>5 A My response is that they showed different results, not</p> <p>6 just the statistical significance being different, but</p> <p>7 the point estimate is different.</p> <p>8 Q Let me put it this way:</p> <p>9 On the question of statistical significance, yes or</p> <p>10 no, are the results-- the combined results of the</p> <p>11 case-controls consistent with the combined results on the</p> <p>12 cohort studies or not, yes or no?</p> <p>13 MS. PARFITT: Objection; form, asked</p> <p>14 and answered.</p> <p>15 THE WITNESS: So I think I answered</p> <p>16 before, the statistical significance was different and</p> <p>17 they showed different results.</p> <p>18 Q (By Mr. Williams) And the different results that they</p> <p>19 showed was that one, the cohorts, was not statistically</p> <p>20 significant, and the case-controls, overall, were</p> <p>21 statistically significant, correct?</p> <p>22 MS. PARFITT: Objection; form, asked</p> <p>23 and answered multiple times.</p> <p>24 THE WITNESS: So I answered more</p> <p>25 fully, I think, than just statistical significance.</p>
<p style="text-align: right;">Page 247</p> <p>1 A That's correct.</p> <p>2 Q The combined risk estimate for the cohort studies, on the</p> <p>3 other hand, did not come out to a statistically</p> <p>4 significant number, right?</p> <p>5 A That's correct.</p> <p>6 Q Can we agree that on the question of statistical</p> <p>7 significance, the combined risk estimate for the</p> <p>8 case-control studies are not consistent with the combined</p> <p>9 risk estimate for the cohort studies?</p> <p>10 MS. PARFITT: Objection; form, asked</p> <p>11 and answered, misstates her prior testimony.</p> <p>12 You may answer.</p> <p>13 THE WITNESS: The combined cohort</p> <p>14 study not only was not significant, the relative risk was</p> <p>15 1.02.</p> <p>16 Q (By Mr. Williams) I don't believe you answered my</p> <p>17 question.</p> <p>18 My question is:</p> <p>19 Can we agree that a question of statistical</p> <p>20 significance, just that question, the combined risk</p> <p>21 estimate for the case-control studies are not consistent</p> <p>22 with the combined risk estimate for the cohort studies</p> <p>23 because for the cohort studies the result was not</p> <p>24 statistically significant, and for the case-control</p> <p>25 studies the combined estimate was statistically</p>	<p style="text-align: right;">Page 249</p> <p>1 I answered both about the relative risk, which is</p> <p>2 the point estimate, and the statistical significance, so</p> <p>3 the point estimate was 1.02 in the cohort studies, not</p> <p>4 statistically significant.</p> <p>5 It was 1.26 in the case-control studies, and that</p> <p>6 was statistically significant.</p> <p>7 Q (By Mr. Williams) Perhaps that's where the issue is.</p> <p>8 For purposes of my question, I am asking you to</p> <p>9 limit your analysis to the question of statistical</p> <p>10 significance.</p> <p>11 Are you with me so far?</p> <p>12 A I understand what you're saying.</p> <p>13 Q With respect to statistical significance, with respect to</p> <p>14 that issue, is it your testimony that the case-control</p> <p>15 studies, which find that there is a statistically</p> <p>16 significant positive odds ratio or relative risk, and the</p> <p>17 cohort studies, which do not collectively have a positive</p> <p>18 relative risk, is it your testimony that those are</p> <p>19 consistent with respect to the issue of statistical</p> <p>20 significance?</p> <p>21 MS. PARFITT: Objection; form, asked</p> <p>22 and answered, hopefully for the last time.</p> <p>23 THE WITNESS: And I think I don't look</p> <p>24 at statistical significance in the same way for a</p> <p>25 relative risk of 1.02 as I do for 1.26, but there is</p>

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<p>1 something remarkable here, is that the upper limit of the</p> <p>2 confidence interval for the cohort studies is almost up</p> <p>3 to the relative risk for the case-control studies, so the</p> <p>4 statistical significance test tells us the relative risk</p> <p>5 could be as high as 1.2, so even though you call it</p> <p>6 nonstatistically significant, it's still within 95</p> <p>7 percent chance that it's up at 1.2.</p> <p>8 Q (By Mr. Williams) Are they both statistically</p> <p>9 significant or not, the case-controls or the-- and the</p> <p>10 cohort studies?</p> <p>11 MS. PARFITT: Objection; form, asked</p> <p>12 and answered.</p> <p>13 Counsel, I do believe she is trying to answer the</p> <p>14 question.</p> <p>15 This is about the tenth time.</p> <p>16 Q (By Mr. Williams) You may answer.</p> <p>17 MS. PARFITT: Give your response</p> <p>18 again.</p> <p>19 THE WITNESS: I think I'm sorry, but I</p> <p>20 don't think of something as just looking at the</p> <p>21 statistical significance.</p> <p>22 I always look at both the relative risk and the</p> <p>23 statistical significance.</p> <p>24 Repeating, the relative risk is only 1.2 for the</p> <p>25 cohort studies.</p>	<p>1 Just so we can remember, my question to you is:</p> <p>2 Are you unable to answer my question because I am</p> <p>3 limiting the question to talk about statistical</p> <p>4 significance and whether those findings are consistent or</p> <p>5 inconsistent?</p> <p>6 MS. PARFITT: Objection; form.</p> <p>7 Answer his question.</p> <p>8 You have answered multiple times.</p> <p>9 THE WITNESS: I think my answer is I</p> <p>10 don't look at just statistical significance. I look at</p> <p>11 point estimate as well.</p> <p>12 Q (By Mr. Williams) Are you an expert in asbestos?</p> <p>13 A No, I'm not an expert in asbestos.</p> <p>14 Q Are you an expert in geology?</p> <p>15 A No.</p> <p>16 Q Mineralogy?</p> <p>17 A No.</p> <p>18 Q Can you distinguish between an asbestiform fiber on the</p> <p>19 one hand and a cleavage fragment on the other?</p> <p>20 A No.</p> <p>21 Q Can you distinguish between an asbestiform and a</p> <p>22 nonasbestiform fiber?</p> <p>23 A No.</p> <p>24 Q Are you an expert in microscopy?</p> <p>25 A In which?</p>
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<p>1 The confidence interval includes one, so that would</p> <p>2 be considered not statistically significant, but it</p> <p>3 ranges up to 1.2, which means the relative risk could be</p> <p>4 as high as 1.2 for the cohort studies.</p> <p>5 Q (By Mr. Williams) You're speculating; are you not?</p> <p>6 MS. PARFITT: Objection; form.</p> <p>7 THE WITNESS: I'm interpreting--</p> <p>8 MS. PARFITT: Misstates your</p> <p>9 testimony.</p> <p>10 THE WITNESS: I am interpreting what</p> <p>11 the 95 percent confidence intervals mean.</p> <p>12 It's not a speculation.</p> <p>13 Q (By Mr. Williams) Is the answer that you are not able to</p> <p>14 answer my question as phrased when I limit the question</p> <p>15 to an analysis of statistical significance?</p> <p>16 MS. PARFITT: Objection; form.</p> <p>17 She has answered your question completely.</p> <p>18 Let's move on, Mr. Williams.</p> <p>19 You are not going to get a different answer.</p> <p>20 You can use up the remaining of your time if you</p> <p>21 would like, but she has answered the question.</p> <p>22 Q (By Mr. Williams) You may answer, Doctor.</p> <p>23 MS. PARFITT: You are asking questions</p> <p>24 10, 15 times--</p> <p>25 Q (By Mr. Williams) You may answer.</p>	<p>1 Q Microscopy.</p> <p>2 A No.</p> <p>3 Q Are you qualified to analyze bulk samples of baby powder</p> <p>4 using different types of microscopes?</p> <p>5 A No, I'm not.</p> <p>6 Q Are you qualified to perform any of the following tests</p> <p>7 for purposes of analyzing a talcum powder sample:</p> <p>8 X-ray defraction?</p> <p>9 A Are you going to list them or do you want me to say</p> <p>10 "no"--</p> <p>11 Q You can answer them one at a time.</p> <p>12 A No.</p> <p>13 Q Polarized light microscopy?</p> <p>14 A No.</p> <p>15 Q Transmission electron microscopy?</p> <p>16 A No.</p> <p>17 Q In your work do you review and analyze other people's</p> <p>18 defraction patterns or readouts or images or other</p> <p>19 results of microscopic testing for-- of talcum powder for</p> <p>20 asbestos, the presence of asbestos?</p> <p>21 A Are you talking about looking at the details of their</p> <p>22 sampling?</p> <p>23 Q Correct.</p> <p>24 A To determine the methods? No, I would not do that.</p> <p>25 Q Regardless of the method, have you ever personally tested</p>

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<p style="text-align: right;">Page 254</p> <p>1 any talcum powder product for asbestos?</p> <p>2 A No.</p> <p>3 Q Have you ever been to a talc mine?</p> <p>4 A No.</p> <p>5 Q How about a talc mill?</p> <p>6 A No.</p> <p>7 Q Do you know how talc is selected from a mine, sorted,</p> <p>8 sterilized, processed before it is ever put into a bottle</p> <p>9 of Johnson's Baby Powder?</p> <p>10 A No, I don't.</p> <p>11 Q Do you know what methods are used to test the cosmetic</p> <p>12 talc in Johnson's Baby Powder products for asbestos?</p> <p>13 A Are you talking about what your company methods are to</p> <p>14 test?</p> <p>15 Q Whether it was the company's methods or someone else's--</p> <p>16 A No.</p> <p>17 Q Do you know how many methods were used over the years to</p> <p>18 test cosmetic talc in Johnson's Baby Powder products for</p> <p>19 asbestos?</p> <p>20 A In some of the documents I've reviewed, I have seen</p> <p>21 mention of several types, but I couldn't-- I am not an</p> <p>22 expert in them.</p> <p>23 Q Do you know how often cosmetic talc, in Johnson's Baby</p> <p>24 Powder products, were tested for asbestos?</p> <p>25 A By anybody, I don't know.</p>	<p style="text-align: right;">Page 256</p> <p>1 2014 have shown that present-day talcum powder products</p> <p>2 include several types of asbestos, and you cite two</p> <p>3 sources, right?</p> <p>4 A Yes.</p> <p>5 Q And those are Gordon 2014 and Blount 1991?</p> <p>6 A That's correct.</p> <p>7 Q You also cite to Exhibit No. 47 of the deposition of</p> <p>8 Imerys witness Julie Pier, P-I-E-R.</p> <p>9 Do you remember that?</p> <p>10 A Yes.</p> <p>11 Q And to Exhibit No. 24 to the deposition of Johnson &</p> <p>12 Johnson witness John Hopkins, correct?</p> <p>13 A Yes.</p> <p>14 Q You also have cited to five litigation reports. Those</p> <p>15 are referenced as 79 to 83, which were prepared by</p> <p>16 Dr. William Longo, right?</p> <p>17 A Yes.</p> <p>18 Q Are you in fact relying upon Gordon 2014, Blount 1991,</p> <p>19 Pier Exhibit No. 47, Hopkins Exhibit No. 24, and the five</p> <p>20 Longo reports for your opinion that asbestos has been</p> <p>21 found specifically in Johnson's Baby Powder products?</p> <p>22 A I would have to look at Gordon again to see what that</p> <p>23 said about Johnson & Johnson.</p> <p>24 Blount did identify one of the components as baby</p> <p>25 powder.</p>
<p style="text-align: right;">Page 255</p> <p>1 Q Is it your opinion that at one point in time or another,</p> <p>2 Johnson's Baby Powder products contained asbestos?</p> <p>3 I think you told us you believe that's true,</p> <p>4 correct?</p> <p>5 A Yes, that is my opinion.</p> <p>6 Q I will rephrase.</p> <p>7 Is it your opinion that Johnson's Baby Powder</p> <p>8 products sold today contain asbestos?</p> <p>9 MS. PARFITT: Objection; form, asked</p> <p>10 and answered.</p> <p>11 THE WITNESS: I believe from the</p> <p>12 evidence I've seen, that there was asbestos as recently</p> <p>13 as samples tested in the 2000s.</p> <p>14 I don't know for 2019.</p> <p>15 I haven't seen any reports on that.</p> <p>16 Q (By Mr. Williams) And am I right-- if you take a look at</p> <p>17 Page 57 of your report, Exhibit No. 2, and I'm referring</p> <p>18 you to the bottom of the page, the last paragraph, does</p> <p>19 that paragraph summarize your opinion that asbestos has</p> <p>20 been found in Johnson's Baby Powder products</p> <p>21 specifically?</p> <p>22 A So are you talking about the whole paragraph?</p> <p>23 Q Correct.</p> <p>24 You mention Reference No. 75 and Reference No. 76 as</p> <p>25 supporting the idea that published data as recently as</p>	<p style="text-align: right;">Page 257</p> <p>1 Pier and Hopkins were Johnson & Johnson products,</p> <p>2 and Longo tested products from-- my understanding from</p> <p>3 the report, from Johnson & Johnson.</p> <p>4 Q Other than the materials that we just identified, are you</p> <p>5 relying on anything else to support your opinion that</p> <p>6 asbestos has been found specifically in Johnson's Baby</p> <p>7 Powder products?</p> <p>8 A No.</p> <p>9 Q "No," you are not relying on anything else?</p> <p>10 A No, I'm not.</p> <p>11 Q Are you aware that at the time they authored the article</p> <p>12 identified as Reference No. 75 -- that's the Gordon 2014</p> <p>13 report -- that each of the three authors had been a paid</p> <p>14 expert for the plaintiffs' lawyers in talcum powder</p> <p>15 litigation?</p> <p>16 A I believe they said that in their disclosures.</p> <p>17 Do we have 75 available?</p> <p>18 Q While they are looking for that, Doctor, do you recall</p> <p>19 whether they identified in the Gordon 2014 article, and</p> <p>20 by "they," I mean the authors, did they identify whether</p> <p>21 they were plaintiff experts; that is, experts retained by</p> <p>22 plaintiffs in litigation.</p> <p>23 A It says, "Attorneys for the litigation process."</p> <p>24 Q It does not say whether it's Plaintiff or Defendant,</p> <p>25 correct?</p>

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<p>1 A I don't see it here--</p> <p>2 Q I'm sorry, what was--</p> <p>3 A It doesn't say for the plaintiff or the defense. It</p> <p>4 doesn't say which.</p> <p>5 Q Do you know, one way or the other, whether the product</p> <p>6 tested in that article was Johnson's Baby Powder?</p> <p>7 A No, I can't recall if I saw it.</p> <p>8 My paragraph didn't talk about Johnson & Johnson,</p> <p>9 just talked about talcum powder products.</p> <p>10 Q Okay. Let me ask you to assume, for purposes of my next</p> <p>11 question, that the product that is referred to in the</p> <p>12 Gordon article was not Johnson's Baby Powder.</p> <p>13 Will you make that assumption for purposes only of</p> <p>14 my question?</p> <p>15 A Okay.</p> <p>16 Q Okay. How would an article about a different talcum</p> <p>17 powder product than the ones that are at issue in this</p> <p>18 case support your opinion that perineal use of Johnson's</p> <p>19 Baby Powder products cause ovarian cancer?</p> <p>20 MS. PARFITT: Objection; form.</p> <p>21 THE WITNESS: My opinion was-- from my</p> <p>22 report, my opinion was that talcum powder product use of</p> <p>23 any source increases risk of ovarian cancer.</p> <p>24 Q (By Mr. Williams) Okay. With respect to the Blount</p> <p>25 article, 1991, Reference No. 76 in your report is the</p>	<p>1 Q Let me ask you about John Hopkins.</p> <p>2 You referenced having read some documents that bore</p> <p>3 his name, correct?</p> <p>4 A Yes.</p> <p>5 Q Let's mark as Exhibit No. 19 a document that I believe</p> <p>6 was Reference No. 78 in your report.</p> <p>7 (Exhibit No. 19 marked</p> <p>8 for identification.)</p> <p>9</p> <p>10 Q (By Mr. Williams) Do you recognize this as the document</p> <p>11 in your report that you cited in support of your opinion</p> <p>12 that talcum powder products contained asbestos?</p> <p>13 A Yes.</p> <p>14 Q It is Exhibit No. 24, you see there, with the little tab,</p> <p>15 to John Hopkins' August 17, 2018 deposition, correct?</p> <p>16 A Okay. Here it says "19."</p> <p>17 Q What says 19?</p> <p>18 A I have Exhibit No. 19 for this one, 24 for the--</p> <p>19 Q Correct.</p> <p>20 Just so you know, for this deposition it's Exhibit</p> <p>21 No. 19.</p> <p>22 For Mr. Hopkins' deposition it was Exhibit No. 24.</p> <p>23 Do you understand?</p> <p>24 A Yes.</p> <p>25 Q Is this one of the documents that Plaintiffs' counsel</p>
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<p>1 article by author A.M. Blount.</p> <p>2 Do you recall that?</p> <p>3 A Yes.</p> <p>4 Q What information from the Blount 1991 article are you</p> <p>5 relying on for your opinion that the contaminated</p> <p>6 products mentioned in that article refer to Johnson's</p> <p>7 Baby Powder products?</p> <p>8 A So there was a table with unidentified samples labelled A</p> <p>9 to O, and I is indicated as-- somewhere it's written as</p> <p>10 baby powder, I believe.</p> <p>11 Then from litigation there was some indication of</p> <p>12 what these different samples were, and so that one was</p> <p>13 identified as Johnson & Johnson Baby Powder.</p> <p>14 Q Did you review the entirety of Dr. Blount's deposition?</p> <p>15 A No. I skimmed part of it. I didn't review-- I skimmed</p> <p>16 part of it. I didn't read the total deposition.</p> <p>17 Q Did you read the part of the deposition where Dr. Blount</p> <p>18 testified that the bottle of Johnson's Baby Powder that</p> <p>19 she brought to the deposition could not possibly be the</p> <p>20 bottle of talc that she identified as Sample No. 1 in her</p> <p>21 1991 article?</p> <p>22 A You mean Sample I or Sample I?</p> <p>23 Q Sample I, thank you.</p> <p>24 It's Roman I or I.</p> <p>25 A I didn't read that, no.</p>	<p>1 sent to you without your asking?</p> <p>2 MS. PARFITT: Objection; form.</p> <p>3 THE WITNESS: They did send it to me.</p> <p>4 I don't recall if I asked for it or not.</p> <p>5 Q (By Mr. Williams) Do you have any idea if the three</p> <p>6 pages of testing contained in Mr. Hopkins' Exhibit No. 24</p> <p>7 is representative of all the testing that was done on</p> <p>8 Johnson & Johnson talcum powder products?</p> <p>9 A I don't, but I would be concerned about any bottles</p> <p>10 having asbestos in them.</p> <p>11 Q Do you have a problem with the notion that the seller of</p> <p>12 talcum powder products tests for asbestos?</p> <p>13 MS. PARFITT: Objection; form.</p> <p>14 THE WITNESS: Do I have a problem with</p> <p>15 the notion that the seller tests--</p> <p>16 Q (By Mr. Williams) I'll rephrase it.</p> <p>17 A No, I don't have a problem.</p> <p>18 Q And the reason you don't have a problem is that the</p> <p>19 seller of a product could, in all good faith, seek to</p> <p>20 determine whether or not a particular mine where they're</p> <p>21 getting the product contains asbestos, right?</p> <p>22 MS. PARFITT: Objection; form.</p> <p>23 THE WITNESS: Okay.</p> <p>24 Q (By Mr. Williams) So the mere fact-- what I'm getting at</p> <p>25 is:</p>

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<p>1 The mere fact that a company tests to determine 2 whether or not there is asbestos, for example, in a mine 3 where they are mining for talcum powder, that fact, in 4 and of itself, is not repugnant to you in any way, 5 correct? 6 A No. 7 MS. PARFITT: Objection; form. 8 Q (By Mr. Williams) It is not repugnant to you, for 9 example, for a car company to test whether cars of a 10 particular make and model have brakes that work, right? 11 A Correct. 12 Q The fact that they test for brakes does not mean that the 13 brakes do not work, right? 14 A Correct. 15 Q The fact that they test for brakes doesn't mean that the 16 product that is actually sold to people does not have 17 brakes that can stop a car, right? 18 MS. PARFITT: Objection; form. 19 THE WITNESS: There are a couple of 20 negatives there. I'm just getting a little confused. 21 Q (By Mr. Williams) I will start over. 22 The mere fact that a car company tests its makes and 23 models to see whether the brakes work does not mean that 24 the cars that are ultimately sold have brakes that do not 25 work?</p>	<p>1 2 Q (By Mr. Williams) Let me show you what we've marked as 3 Exhibit No. D-1-- Exhibit No. 20. Pardon me. 4 MS. PARFITT: Counsel, I have not seen 5 this before. 6 Can you represent to us what this is? 7 MR. WILLIAMS: I will in a second. 8 Q (By Mr. Williams) Have you ever seen this document, 9 Dr. McTiernan, what's been marked as Exhibit No. 20? 10 A I don't think so-- well-- 11 Q Did Plaintiffs' counsel provide this to you? 12 A I don't recall. 13 Q Let me represent to you that this is Exhibit No. D-1, 14 D-1, to John Hopkins October 17, 2018 deposition. 15 Will you accept that representation? 16 A Yes. 17 Q You see the tab number that has-- it bears a deposition 18 tab number just like your deposition has exhibits with 19 tabs? 20 A Yes. 21 Q Do you see that Exhibit D-1 appears to contain the same 22 information as Hopkins' Exhibit No. 24, which you were 23 provided by Plaintiffs' counsel, except there's an 24 additional column that says "The whole story"? 25 A I think there's an awful lot of information here.</p>
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<p>1 A Correct. 2 Q Do you know whether this Exhibit No. 24 that's in front 3 of you, from Dr. Hopkins, represents final or preliminary 4 test results? 5 MS. PARFITT: Objection; form. 6 THE WITNESS: Final or preliminary? 7 Can you explain that, meaning-- what do you mean by 8 those two? 9 Q (By Mr. Williams) Do you know the difference between a 10 preliminary test and a final test? 11 A I mean, in terms of what it means for the company, I 12 don't know what final or preliminary would mean in terms 13 of their testing procedures. 14 Q Do you know, one way or the other, if any of the results 15 were updated or corrected? 16 MS. PARFITT: Objection; form. 17 THE WITNESS: Updated for a particular 18 sample or updated for all of their products? 19 Q (By Mr. Williams) Either. 20 A I think I'm confused. 21 I see what was tested for this, and it says Shower 22 to Shower, medicated powder, baby powder, so I would 23 assume that that's an actual product. 24 (Exhibit No. 20 marked 25 for identification.)</p>	<p>1 Q Let's take a couple-- let's take the first one at the top 2 of the page. 3 Under "The whole story," it says, "Tremolite is not 4 asbestos." 5 Do you see that? 6 A Yes. 7 Q And you don't know, as you sit here, whether tremolite is 8 or is not asbestos, right? 9 MS. PARFITT: Objection; misstates her 10 testimony. 11 THE WITNESS: I am confused about that 12 because IARC states that tremolite is asbestos, so-- 13 Q (By Mr. Williams) We'll get to that in a minute. 14 Is it your testimony that the IARC monograph does 15 not make any distinction between a mineral known as 16 tremolite and one known as tremolite asbestos? 17 MS. PARFITT: Objection; form, 18 misstates her testimony. 19 THE WITNESS: I don't recall. We 20 would have to read it. 21 Q (By Mr. Williams) You don't remember one way or another? 22 A No. 23 Q Do you see the last line on the first page refers to, in 24 this same document, Exhibit No. 20 to your deposition, 25 D-1 to Dr. Hopkins' deposition, it refers to trace</p>

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<p>1 amounts of fibrous minerals, but "The whole story" column</p> <p>2 indicates that that does not mean asbestos?</p> <p>3 MS. PARFITT: Objection.</p> <p>4 Is that what it says?</p> <p>5 Is that the question?</p> <p>6 Q (By Mr. Williams) Do you see that that's what it says?</p> <p>7 A It says, "Fibrous minerals does not mean asbestos," so--</p> <p>8 is it fibrous talc? That could be carcinogenic as well.</p> <p>9 Is that correct?</p> <p>10 Q Do you know the difference between fibrous talc and</p> <p>11 fibrous minerals?</p> <p>12 A I couldn't distinguish myself. I'm not a mineralogist,</p> <p>13 no.</p> <p>14 Q What's the basis for your testimony?</p> <p>15 I think you were suggesting a moment ago that</p> <p>16 fibrous talc is somehow carcinogenic.</p> <p>17 Is that what you were suggesting?</p> <p>18 A I believe that IARC considers that it could be, so I</p> <p>19 would have to look at the IARC report again to fully</p> <p>20 report.</p> <p>21 Q So the basis for your testimony then is that you believe</p> <p>22 that IARC states that fibrous talc is carcinogenic?</p> <p>23 A Yes, but I need to look at the report again.</p> <p>24 Q Okay. You are relying on five litigation reports</p> <p>25 authored or co-authored by Dr. Longo as part of his paid</p>	<p>1 Q Do you know one way or the other whether the samples that</p> <p>2 Dr. Longo tested were open and unsealed when he received</p> <p>3 them?</p> <p>4 A I don't recall reading that.</p> <p>5 I would have to look at the report again.</p> <p>6 Q Do you know that Dr. Longo did not personally test any of</p> <p>7 the samples he reports on in the litigation documents</p> <p>8 that you relied on in the case?</p> <p>9 MS. PARFITT: Objection; misstates the</p> <p>10 record.</p> <p>11 THE WITNESS: I just read the summary</p> <p>12 report, which looked like his company did the testing.</p> <p>13 Q (By Mr. Williams) Please turn to Page 57 of your report.</p> <p>14 I want to focus your attention on the fourth</p> <p>15 paragraph there that starts with the word "Asbestos."</p> <p>16 A Yes.</p> <p>17 Q Does that paragraph accurately summarize the bases of</p> <p>18 your opinion that asbestos is established as a cause of</p> <p>19 epithelial ovarian cancer?</p> <p>20 A Yes.</p> <p>21 Q You cite the 2011 Camargo, C-A-M-A-R-G-O, and the 2011</p> <p>22 Reid, R-E-I-D, meta-analyses in support of your opinion</p> <p>23 that asbestos is a cause of ovarian cancer, correct?</p> <p>24 A Yes.</p> <p>25 Q Those are References 71 and 72, right?</p>
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<p>1 expert work for plaintiff lawyers in talcum powder</p> <p>2 litigation, correct?</p> <p>3 MS. PARFITT: Objection; form.</p> <p>4 THE WITNESS: Correct.</p> <p>5 Q (By Mr. Williams) Do you know-- do you think the chain</p> <p>6 of custody is important when it comes to samples that are</p> <p>7 being tested for asbestos?</p> <p>8 Do you know what I mean when I say "chain of</p> <p>9 custody"?</p> <p>10 A Why don't you explain it.</p> <p>11 Q Sure.</p> <p>12 I will ask you to assume that "chain of custody"</p> <p>13 refers to who has custody of a particular substance or</p> <p>14 item that is going to be tested from the time that it</p> <p>15 existed at its source to the time that it is tested.</p> <p>16 Do you understand what I mean?</p> <p>17 A Yes.</p> <p>18 Q Do you know where Dr. Longo got the samples that he</p> <p>19 tested?</p> <p>20 A I understood from the summaries in the beginnings of</p> <p>21 these reports that he received the samples from Johnson &</p> <p>22 Johnson.</p> <p>23 Q All of the samples?</p> <p>24 A I would have to look at the individual reports to</p> <p>25 determine that.</p>	<p>1 A Yes.</p> <p>2 Q You also cite Ferrante, F-E-R-R-A-N-T-E, a 2017 pooled</p> <p>3 analysis, in support of your opinion that asbestos is a</p> <p>4 cause of ovarian cancer, right?</p> <p>5 A Yes.</p> <p>6 Q You also cite to the IARC 2012 monograph on asbestos, an</p> <p>7 article by members of the IARC working group, correct?</p> <p>8 A Yes.</p> <p>9 Q Other than those materials, are you relying on anything</p> <p>10 else to support your opinion that asbestos is a cause of</p> <p>11 ovarian cancer?</p> <p>12 A No, I don't believe so, and I did not do a full</p> <p>13 systematic search with causal analysis for asbestos.</p> <p>14 I only did that for talcum powder products.</p> <p>15 Q Why didn't you do one for asbestos?</p> <p>16 A I wasn't asked to.</p> <p>17 Q Were you asked to include a discussion of asbestos in</p> <p>18 your report at all-- excuse me--</p> <p>19 A I was asked to respond about mechanisms-- sorry, to talk</p> <p>20 about mechanisms that may be explaining the association</p> <p>21 between talcum powder products and ovarian cancer risk,</p> <p>22 and when I looked at mechanisms, I often would see the</p> <p>23 potential for asbestos being included in talcum powder</p> <p>24 products, so I wanted to include that as one possible</p> <p>25 mechanism, especially given that asbestos is a known</p>

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<p>1 carcinogen.</p> <p>2 Q Let me focus your attention on Page 57 of your report,</p> <p>3 Exhibit No. 2, to the last sentence in that fourth</p> <p>4 paragraph that says, "IARC concluded that asbestos,</p> <p>5 fibrous talc, chromium, and nickel are Group 1 human</p> <p>6 carcinogens. IARC also classified cobalt as a 2B</p> <p>7 'possible' carcinogen."</p> <p>8 Do you see that?</p> <p>9 A Yes.</p> <p>10 Q Do you believe that Johnson's Baby Powder products</p> <p>11 contained chromium, nickel, and cobalt?</p> <p>12 A I would have to review some of these documents that</p> <p>13 talked about these--</p> <p>14 Q What are you relying on?</p> <p>15 MS. PARFITT: Please let her finish</p> <p>16 the answer.</p> <p>17 MR. WILLIAMS: I'm sorry.</p> <p>18 THE WITNESS: I would need to review</p> <p>19 the documents in the report responding to that.</p> <p>20 Q (By Mr. Williams) Are those heavy metals, the three</p> <p>21 metals I mentioned, the metals that you believe are or</p> <p>22 have ever been present in Johnson's Baby Powder products?</p> <p>23 MS. PARFITT: Objection; form.</p> <p>24 THE WITNESS: Again, I would have to</p> <p>25 review the documents.</p>	<p>1 you have evidence, do you believe that Johnson's Baby</p> <p>2 Powder in particular contains chromium, nickel, and</p> <p>3 cobalt?</p> <p>4 MS. PARFITT: Objection.</p> <p>5 THE WITNESS: I don't have evidence</p> <p>6 one way or the other.</p> <p>7 I did not look at that.</p> <p>8 I looked only at the general comments that talcum</p> <p>9 powder products could contain these metals.</p> <p>10 I did not look at Johnson & Johnson.</p> <p>11 Q (By Mr. Williams) Thank you.</p> <p>12 Are any of your opinions dependent on the assumption</p> <p>13 that the chemicals in the fragrance that goes into</p> <p>14 Johnson's Baby Powder products are carcinogenic?</p> <p>15 A I read one review by Dr. Crowley (Phonetic) who indicated</p> <p>16 that there were quite a few fragrances in these products</p> <p>17 that fall into the classification of carcinogenicity.</p> <p>18 Without that data, my opinion would still stand.</p> <p>19 Q Dr. Crowley is another expert Plaintiffs' witness that</p> <p>20 Plaintiffs' counsel has paid in connection with talc</p> <p>21 litigation, correct?</p> <p>22 MS. PARFITT: Objection; form.</p> <p>23 THE WITNESS: To my knowledge, yes.</p> <p>24 Q (By Mr. Williams) Have you ever met or spoken with</p> <p>25 Dr. Crowley?</p>
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<p>1 Q (By Mr. Williams) As you sit here today, you are not</p> <p>2 able to tell us what the heavy metals are that are</p> <p>3 supposedly contained in Johnson's Baby Powder?</p> <p>4 MS. PARFITT: Objection; misstates her</p> <p>5 testimony, form.</p> <p>6 THE WITNESS: I would want to review</p> <p>7 the documents.</p> <p>8 Q (By Mr. Williams) Let me ask you this:</p> <p>9 Is it your opinion today, Doctor, that Johnson's</p> <p>10 Baby Powder products contain chromium, nickel, and</p> <p>11 cobalt?</p> <p>12 A Again, I would need to look at the documents to see what</p> <p>13 was found.</p> <p>14 Q So you can't state whether you have that opinion or not?</p> <p>15 MS. PARFITT: Objection. She needs to</p> <p>16 look at the document.</p> <p>17 What documents do you need to see?</p> <p>18 THE WITNESS: I would want to see-- I</p> <p>19 guess Longo-- whoever was looking at these to see what</p> <p>20 was there, but my paragraph did not talk about Johnson &</p> <p>21 Johnson.</p> <p>22 My paragraph talked about talcum powder products</p> <p>23 having these constituents.</p> <p>24 Q (By Mr. Williams) That's my point.</p> <p>25 So as you sit here today, based on your review, do</p>	<p>1 A No, I have not.</p> <p>2 Q Are you relying on Dr. Crowley's litigation report for</p> <p>3 your opinion that perineal use of Johnson's Baby Powder</p> <p>4 products can cause ovarian cancer?</p> <p>5 A Yes, I have looked at his report.</p> <p>6 Q What chemicals did Dr. Crowley identify as fragrance</p> <p>7 constituents contained in Johnson's Baby Powder products?</p> <p>8 A There were many.</p> <p>9 I would have to see the report.</p> <p>10 Do you have it?</p> <p>11 Q I don't want to take the time to do that.</p> <p>12 Let me just ask you this:</p> <p>13 Did you do anything to independently verify whether</p> <p>14 those constituents are, in fact, contained in Johnson's</p> <p>15 Baby Powder products?</p> <p>16 A No, I did not.</p> <p>17 Q We have talked a little bit about IARC today, and I want</p> <p>18 to ask you some questions about that.</p> <p>19 You are familiar with the International Agency for</p> <p>20 Research on Cancer, right?</p> <p>21 A Yes, I am.</p> <p>22 Q You have done work with them?</p> <p>23 A Yes.</p> <p>24 Q IARC has five different categories it places substances</p> <p>25 into with respect to whether they are or may be</p>

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<p style="text-align: right;">Page 274</p> <p>1 carcinogenic, correct?</p> <p>2 A I can't respond to whether it's exactly five or not.</p> <p>3 I have looked at these-- do we have a list of them?</p> <p>4 Q Sure.</p> <p>5 It is-- we'll mark it as Exhibit No. 21.</p> <p>6 (Exhibit No. 21 marked</p> <p>7 for identification.)</p> <p>8</p> <p>9 Q (By Mr. Williams) This is the IARC monograph on talc.</p> <p>10 A 2012?</p> <p>11 Q This one is 2010.</p> <p>12 A 2010, okay.</p> <p>13 Q Let me refer you to Page 35 of the document.</p> <p>14 Do you see "Group 2B" listed there?</p> <p>15 A Yes.</p> <p>16 Q That is where the agent is possibly carcinogenic to</p> <p>17 humans, and then there is a fairly long description of</p> <p>18 what that means.</p> <p>19 Do you see that?</p> <p>20 A Yes.</p> <p>21 Q And it is your understanding that talc has been listed as</p> <p>22 a Group 2B substance?</p> <p>23 A Yes.</p> <p>24 You are using data up to 2006, yes.</p> <p>25 Q Of the almost 1000 substances that IARC has reviewed, do</p>	<p style="text-align: right;">Page 276</p> <p>1 review.</p> <p>2 Q Okay. And let me refer you to Page 35 again, under Group</p> <p>3 2B where that's the definition of the agent being</p> <p>4 possibly carcinogenic to humans.</p> <p>5 Do you see that?</p> <p>6 A Yes.</p> <p>7 Q It says, "This category is used for agents for which</p> <p>8 there is limited evidence of carcinogenicity in humans</p> <p>9 and less than sufficient evidence of carcinogenicity in</p> <p>10 experimental animals."</p> <p>11 Did I read that right?</p> <p>12 A Yes.</p> <p>13 Q Do you remember, as you sit there, the definition of</p> <p>14 "limited evidence of carcinogenicity" under IARC's</p> <p>15 definitions?</p> <p>16 A No, I don't.</p> <p>17 Q Take a look at Page 31.</p> <p>18 On Page 31 of Exhibit No. 21, there is a definition</p> <p>19 at the bottom of the page for "limited evidence of</p> <p>20 carcinogenicity," right?</p> <p>21 A Yes.</p> <p>22 Q And it says, "A positive association has been observed</p> <p>23 between exposure to the agent and cancer for which a</p> <p>24 causal interpretation is considered by the working group</p> <p>25 to be credible, but chance, bias, or confounding could</p>
<p style="text-align: right;">Page 275</p> <p>1 you know how many have been classified as Group 4, which</p> <p>2 is on the next page, "The agent is probably not</p> <p>3 carcinogenic to humans"?</p> <p>4 A No, I haven't.</p> <p>5 Q If I were to represent to you that there was one, and</p> <p>6 only one, substance that they have reviewed that was put</p> <p>7 into Group 4, would that surprise you?</p> <p>8 MS. PARFITT: Objection; form.</p> <p>9 THE WITNESS: It would not surprise me</p> <p>10 because they probably are only looking at things that are</p> <p>11 potentially carcinogenic.</p> <p>12 Q (By Mr. Williams) You mentioned earlier today that IARC</p> <p>13 sets a high bar for listing something as a Group 2B</p> <p>14 possible substance.</p> <p>15 Do you remember saying that?</p> <p>16 A I don't, but I believe you.</p> <p>17 Q What was the basis for your statement that IARC sets a</p> <p>18 high bar as opposed to some other level bar for</p> <p>19 determining whether a substance is a Group 2B substance?</p> <p>20 A From my understanding, they do a systematic review. They</p> <p>21 set up a panel of scientists, and then they do a</p> <p>22 systematic review, including studies from humans and</p> <p>23 animals, and they did this for-- for talcum powder</p> <p>24 products-- for talc, they did it up to 2006, and they did</p> <p>25 not do meta-analysis, but they did do a systematic</p>	<p style="text-align: right;">Page 277</p> <p>1 not be ruled out with reasonable confidence."</p> <p>2 Did I read that right?</p> <p>3 A Yes.</p> <p>4 Q Remember earlier today we were talking about chance,</p> <p>5 bias, and confounding factors needing to be ruled out in</p> <p>6 order to move something from a Group 2B designation to a</p> <p>7 higher designation, and you said, "I would have to look</p> <p>8 at the IARC monograph"?</p> <p>9 Do you remember that?</p> <p>10 A Yes.</p> <p>11 Q Now that we are looking at the IARC monograph, and you</p> <p>12 see the definition of "limited evidence of</p> <p>13 carcinogenicity," will you agree with me now that in</p> <p>14 order for something to move up from this Level 2B, where</p> <p>15 there's limited evidence of carcinogenicity in humans, to</p> <p>16 some higher level, one would need to rule out or</p> <p>17 specifically the IARC group would need to rule out</p> <p>18 chance, bias, and confounding?</p> <p>19 MS. PARFITT: Objection; form.</p> <p>20 THE WITNESS: Yes, because they state</p> <p>21 that in the category above, "Sufficient."</p> <p>22 Q (By Mr. Williams) And when you say "yes," "yes," they</p> <p>23 would have to rule out all of those things, correct?</p> <p>24 A Yes, with reasonable confidence.</p> <p>25 Q Now, as we sit here today, IARC still lists talc as a 2B</p>

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<p style="text-align: right;">Page 278</p> <p>1 substance, correct?</p> <p>2 MS. PARFITT: Objection; form.</p> <p>3 THE WITNESS: IARC has not updated</p> <p>4 their 2006 data, correct.</p> <p>5 Q (By Mr. Williams) Therefore the most recent update lists</p> <p>6 talc as a Group 2B substance, correct?</p> <p>7 MS. PARFITT: Objection; form.</p> <p>8 THE WITNESS: Using data up to 2006,</p> <p>9 yes.</p> <p>10 Q (By Mr. Williams) You keep saying, "using data up to</p> <p>11 2006."</p> <p>12 Do you have any basis for-- strike that.</p> <p>13 You testified earlier today that you believe that</p> <p>14 IARC would set a higher designation if they had the</p> <p>15 results of studies since 2006, correct?</p> <p>16 A I believe it would be reasonable to expect that, given</p> <p>17 that there's more studies published since that time.</p> <p>18 Q And when you say that you believe it would be reasonable</p> <p>19 to expect that, you expected it, right?</p> <p>20 MS. PARFITT: Objection.</p> <p>21 THE WITNESS: I can't say what a panel</p> <p>22 of scientists would say if it was faced with reviewing</p> <p>23 the literature.</p> <p>24 All I can say is the literature-- all I can say is</p> <p>25 the literature has been increased significantly in the</p>	<p style="text-align: right;">Page 280</p> <p>1 you relied upon in preparing your report, correct?</p> <p>2 A Yes.</p> <p>3 Q It was published in 2008?</p> <p>4 A Yes.</p> <p>5 Q That is two years after IARC met to discuss talc?</p> <p>6 A Yes.</p> <p>7 Q Three of the four authors of this meta-analysis were</p> <p>8 participants in the IARC working group.</p> <p>9 Do you remember that?</p> <p>10 A Yes.</p> <p>11 Q If you look at the last page of this exhibit, Exhibit</p> <p>12 No. 22, there's an acknowledgments section on Page 360.</p> <p>13 It says, "The work reported in this paper was</p> <p>14 initiated while SH, JS, and EW were part of an IARC</p> <p>15 monograph working group of the International Agency for</p> <p>16 Research on Cancer, Lyon, France."</p> <p>17 Do you see that?</p> <p>18 A Yes.</p> <p>19 Q So after the working group determined, and by that I mean</p> <p>20 the IARC working group determined, that chance, bias, or</p> <p>21 confounding could not be ruled out as an explanation for</p> <p>22 the reported association between talc and ovarian cancer,</p> <p>23 three of the members of that working group continued</p> <p>24 their work in this article, correct?</p> <p>25 MS. PARFITT: Objection; form,</p>
<p style="text-align: right;">Page 279</p> <p>1 last ten years.</p> <p>2 Q (By Mr. Williams) And what study are you referring to or</p> <p>3 studies are you referring to?</p> <p>4 A So some of the larger case-control studies that were</p> <p>5 published in recent years, the two meta-analyses, and the</p> <p>6 pooled analysis.</p> <p>7 Q Anything else?</p> <p>8 A In terms of epidemiology, that's it.</p> <p>9 Q Let me show you to one of the studies that has been done</p> <p>10 since the IARC monograph was first drafted in 2006.</p> <p>11 We'll mark it as Exhibit No. 22.</p> <p>12 (Exhibit No. 22 marked</p> <p>13 for identification.)</p> <p>14</p> <p>15 Q (By Mr. Williams) The Langseth study, which is Exhibit</p> <p>16 No. 22, is one of the studies there you rely upon,</p> <p>17 correct?</p> <p>18 A That's correct.</p> <p>19 Q Let me ask you to turn to Page 360, which is the-- I</p> <p>20 believe the last page of the study.</p> <p>21 Do you see that there are 34 publications cited as</p> <p>22 references to the Langseth article?</p> <p>23 A Yes.</p> <p>24 Q For the record, "Langseth" is L-A-N-G-S-E-T-H.</p> <p>25 The Langseth study was one of the meta-analyses that</p>	<p style="text-align: right;">Page 281</p> <p>1 misstates the substance of this article.</p> <p>2 THE WITNESS: Yes.</p> <p>3 Q (By Mr. Williams) You may answer.</p> <p>4 A Yes.</p> <p>5 Q Does this paper report the perineal use of talc in fact</p> <p>6 causes ovarian cancer?</p> <p>7 A I don't see that they did a full causal analysis in this</p> <p>8 paper, but I see that they have a pooled odds ratio of</p> <p>9 1.35, which is statistically significant.</p> <p>10 Yeah, 1.35.</p> <p>11 Q You read this study, right?</p> <p>12 A Yes.</p> <p>13 Q Let's take a look at Page 359.</p> <p>14 Under the heading "Proposal to research community,"</p> <p>15 do you see that?</p> <p>16 A Yes.</p> <p>17 Q Right underneath that it says, "The current body of</p> <p>18 experimental and epidemiological evidence is insufficient</p> <p>19 to establish a causal association between perineal use of</p> <p>20 talc and ovarian cancer risk."</p> <p>21 Did I read that right?</p> <p>22 A Yes.</p> <p>23 Q Can you and I agree that that is the opposite of the</p> <p>24 conclusion that you are intending to express in this</p> <p>25 litigation?</p>

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<p>1 MS. PARFITT: Objection; form.</p> <p>2 THE WITNESS: Using information</p> <p>3 available to 2018, I do have a different opinion than</p> <p>4 these investigators did in using their data up to 2006.</p> <p>5 Q (By Mr. Williams) They-- strike that.</p> <p>6 They would have information up until the time they</p> <p>7 published this study, the Langseth study, right, which</p> <p>8 was done in 2008?</p> <p>9 MS. PARFITT: Objection.</p> <p>10 THE WITNESS: Not necessarily up until</p> <p>11 this date.</p> <p>12 It takes a while to get-- it was accepted in 2007,</p> <p>13 so their data are going to be studies probably only up to</p> <p>14 2006, if the paper was already written and accepted in</p> <p>15 2007, October.</p> <p>16 Q (By Mr. Williams) After this Langseth paper was</p> <p>17 published, there were large cohort studies, prospective</p> <p>18 studies, that were published, true?</p> <p>19 A They were small in terms of the number of cases.</p> <p>20 They came from large cohorts, but the number of</p> <p>21 cases were small.</p> <p>22 Q Are you referring to the cohort studies that were</p> <p>23 published in 2008, 2010, and 2014?</p> <p>24 MS. PARFITT: Objection; form.</p> <p>25 THE WITNESS: Two thousand-- yes-- how</p>	<p>1 combined?</p> <p>2 MS. PARFITT: Objection; form.</p> <p>3 THE WITNESS: I don't think we had-- I</p> <p>4 don't think we discussed that particular-- and we didn't</p> <p>5 do a power analysis with the numbers that they had, but</p> <p>6 together they had-- what was it, 900, so they probably</p> <p>7 were powered with a relative risk of 1.3.</p> <p>8 Q (By Mr. Williams) Well, whatever that testimony was, it</p> <p>9 was.</p> <p>10 Let me ask you this:</p> <p>11 It is a fact that after the IARC monograph-- strike</p> <p>12 that.</p> <p>13 After-- it is a fact that after the data that</p> <p>14 underlay the IARC monograph, after the Langseth study was</p> <p>15 published in 2008, there were additional cohort studies</p> <p>16 that were published, correct?</p> <p>17 A As well as about eight case-control studies.</p> <p>18 Quite a few studies were published after.</p> <p>19 Q And based upon that, you speculate that if IARC were to</p> <p>20 undertake an analysis of whether talc is causally</p> <p>21 associated with ovarian cancer, that you believe that</p> <p>22 they would change their mind?</p> <p>23 MS. PARFITT: Objection; form.</p> <p>24 THE WITNESS: I speculate it would be</p> <p>25 reasonable for a scientific panel to come up with a</p>
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<p>1 many cases do we have?</p> <p>2 I think we covered that earlier, the number of cases</p> <p>3 that would be needed.</p> <p>4 So Women's Health Initiative published in 2014 had</p> <p>5 429 cases.</p> <p>6 The sister study in 2016 had 154.</p> <p>7 The Nurses' Health Study, which the problem with</p> <p>8 that was they weren't-- they changed their categories</p> <p>9 with exposure, but that one did have a larger number,</p> <p>10 797.</p> <p>11 Q (By Mr. Williams) You remember earlier today we went</p> <p>12 through the whole discussion of whether or not there were</p> <p>13 sufficient number of cases, right?</p> <p>14 A And that was a different discussion that was about the</p> <p>15 pooled analysis-- sorry, the meta-analysis of the cohort</p> <p>16 studies.</p> <p>17 It wasn't about these individual studies.</p> <p>18 Q Let me talk to you now about the meta-analysis of those</p> <p>19 studies that were conducted that are cohort studies.</p> <p>20 Do you have those in mind?</p> <p>21 A Yes.</p> <p>22 Q Do you wish to change any of the testimony that you gave</p> <p>23 earlier today concerning the-- whether or not there was a</p> <p>24 sufficient number of cases, as part of the pooled</p> <p>25 analysis, for the cohort studies to have power if</p>	<p>1 different classification after reviewing the new human</p> <p>2 data that have been available the last ten years.</p> <p>3 MR. WILLIAMS: Let's take one final</p> <p>4 break, if we can.</p> <p>5 VIDEOGRAPHER: Going off the record,</p> <p>6 the time is 4:54 p.m.</p> <p>7 (Recess 4:54 to 5:09 p.m.)</p> <p>8</p> <p>9 VIDEOGRAPHER: We are back on the</p> <p>10 record. The time is 5:09 p.m.</p> <p>11 Q (By Mr. Williams) Dr. McTiernan, just a few more minutes</p> <p>12 from me, and then we have just a couple minutes of</p> <p>13 questioning from Imerys counsel, but I have to do it. I</p> <p>14 have to have you grab the Berge study one more time,</p> <p>15 Exhibit No. 16A.</p> <p>16 Earlier today, this afternoon actually, we had a</p> <p>17 discussion about statistical significance, and I was</p> <p>18 trying to focus you on statistical significance as it</p> <p>19 relates to the cohort studies that are listed on page--</p> <p>20 listed in Figure No. 2 on Page 7 of Exhibit No. 16A.</p> <p>21 Do you have that in front of you?</p> <p>22 A Yes.</p> <p>23 Q And you'll recall that I focused you on the subtotal for</p> <p>24 cohort studies with regard to what the relative risk was</p> <p>25 and the confidence interval, and you noted that it was</p>

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<p>1 1.02 as a relative risk with a confidence interval that 2 goes all the way up to 1.20. 3 Do you recall that? 4 A Yes. 5 Q And when I made the point that it was lacking statistical 6 significance, you said, "But the confidence interval 7 includes one, so that would not be statistically 8 significant, but it ranges up to 1.2, which means that 9 the relative risk could be as high as 1.2 for the cohort 10 study." 11 Do you recall saying that? 12 A Correct. 13 Q It is equally true, based on the confidence interval 14 reported on Page 7, that the relative risks could be as 15 low as 0.85, correct? 16 A That's correct. 17 Q And with respect to each of the case-control studies that 18 did not find statistical significance, first you see 19 Cramer in 1982, that one that had a 0.70 relative risk-- 20 you see that one? 21 A Yes. 22 Q That one had a low-- 23 A That's Hartge. 24 Q That's Hartge, pardon me. I shouldn't have said 25 "Cramer."</p>	<p>1 of the confidence interval was 0.70, correct? 2 A Yes. 3 One thing that all of these studies had in common is 4 they were very small, and you get a very wide confidence 5 interval with these small studies. 6 You notice the larger studies, the confidence 7 intervals, such as Cramer 2016, was 1.14 up to 1.5. 8 That's a much more narrow confidence interval, and that's 9 because it's a larger study. 10 Q So let's focus now on what we were focused on this 11 afternoon, which is the cohort studies. 12 With respect to the cohort studies, in the aggregate 13 the low point was 0.85, correct? 14 A That's correct. 15 Q And those cohort studies, we established earlier today, 16 have a total number of cases that exceeded 1300, right? 17 A Correct. 18 Q That's all I need on that. 19 I wanted to ask you about one of the Bradford Hill 20 elements or factors, the one that has to do with 21 biological plausibility, okay? 22 A Mm-hm. 23 Q Is that a "yes"? 24 A Yes. 25 Q Okay. So can you cite a single study, animal or human,</p>
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<p>1 Let me start again. 2 The first case-control study that did not have a 3 statistically significant relative risk was Hartge 1983, 4 right? 5 A Yes. 6 Q And its lower confidence interval, the low side of that, 7 was 0.83, correct? 8 A You're looking at Whittemore, but I think you're talking 9 about Hartge. 10 Q Sorry, 0.40. 11 A Yes. 12 Q So the relative risk for Hartge could go as low as 0.40, 13 right? 14 A Yes. 15 Q The relative risk for Whittemore could go as low as 0.83, 16 right? 17 A Yes. 18 What it means is a 95 percent chance that the risk 19 is within that range, 0.83 up to 1.74. 20 Q So it could be as high as 1.74 for Whittemore or as low 21 as 0.83? 22 A That's correct. 23 Q And for Booth, the low point was 0.80, correct? 24 A Yes. 25 Q And for the next one, Harlow & Weiss, 1989, the low end</p>	<p>1 that traces externally applied talc up through the 2 reproductive organs to the ovaries? 3 MS. PARFITT: Objection; form. 4 THE WITNESS: So the question is 5 externally applied talc? 6 MR. WILLIAMS: Correct. 7 THE WITNESS: So in humans that would 8 be unethical to do to see if that can move up to the 9 ovaries. 10 In terms of animals-- so in animals, talc was placed 11 in the vaginas, and it moved within four days up to the 12 ovaries. 13 Q (By Mr. Williams) And which study is that? 14 A That's on Henderson 86. 15 Q Okay. Thank you. 16 Anything else? 17 A Let me see. 18 In terms of humans, quite a few have been done with 19 particles of similar size to talc, which was thought to 20 be-- let me try to find where I have these. 21 So it wouldn't have the ethical issue, so inert 22 particles of carbon black were placed in women's vaginas 23 and were found to move in 30 minutes in two of three 24 patients, and that's the Egli study. 25 Q Which one is that?</p>

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<p style="text-align: right;">Page 290</p> <p>1 A Egli, E-G-L-I. 2 Q Anything else? 3 A There was a surgical glove study with starch. 4 There was one radioactive tracer labelled human 5 albumin microspheres placed in-- there was-- 6 radio-labelled albumin was placed in women's vaginas one 7 day before pelvic surgery, and of 14 women, nine showed 8 radioactivity in the fallopian tubes. 9 Q Which study was that? 10 A So that was the Venter, V-E-N-T-E-R. 11 One study on migration of talc-- sorry, no, 12 evaluated powder, so this was a starch powder on surgical 13 gloves that were used to perform pelvic exam in advance 14 of surgery, and they found statistically significant-- so 15 this is the Sjosten study. It's S-J-O-S-T-E-N. 16 Q Anything else? 17 A And that's in terms of migration for humans and animals, 18 I believe. 19 Q So is it accurate to say that not one of the studies that 20 you just mentioned -- Egli, Venter, Sjosten or Henderson 21 -- involves tracing externally applied talc in the 22 perineal area up through the reproductive organs through 23 the ovaries? 24 A There are no such studies in humans, that's correct. 25 It would be unethical to apply it externally and</p>	<p style="text-align: right;">Page 292</p> <p>1 Q But none of the studies that you mentioned involve 2 reviewing perineal use external to the vagina and 3 followed the talc up through the reproductive organs, 4 true or not true? 5 A That's correct. 6 Q Can you cite any published study concluding that 7 particles on the outside of the vagina can migrate inside 8 and up the genital tract to the ovary? 9 A I don't believe it was cited in my report. 10 Q Assuming for a moment that talcum powder can reach the 11 ovaries, is it your opinion that talcum powder produces 12 chronic inflammation that somehow leads to ovarian 13 cancer? 14 A Yes, it is my opinion that it can cause chronic 15 inflammation and it doesn't need to reach the ovaries. 16 Many cancers, especially serous cancers, are thought 17 to begin in the fallopian tubes, and they would need to 18 rise as high as that. 19 Q So inflammation is the biological mechanism that you 20 believe is plausible for perineal talc use to cause 21 ovarian cancer, correct? 22 A I believe it's one very plausible mechanism. 23 Q There are no reports in the literature of externally 24 applied talcum powder products leading to inflammation, 25 granulomas, fibrosis, or adhesions anywhere along a</p>
<p style="text-align: right;">Page 291</p> <p>1 follow it up through the pelvic organs. 2 Q Same with the animals though, none of the animal studies 3 that you just mentioned, or the only animal study you 4 mentioned, does not deal with externally applied talc 5 moving up through the reproductive organs through the 6 ovaries, correct? 7 MS. PARFITT: Object to form. 8 THE WITNESS: They're vaginally 9 applied. 10 Q (By Mr. Williams) In the vagina, correct? 11 A Into the vagina, yes. 12 Q So you and I can agree that there is a difference between 13 the outer area and inside the vagina? 14 MS. PARFITT: Objection. 15 THE WITNESS: There are plenty of ways 16 for which anything on the external part of the peroneum 17 can move into the vagina. 18 Q (By Mr. Williams) There's not one study that you've 19 cited for humans that involved particles other than talc 20 or any known toxic substance. 21 There are articles that inject into the vagina the 22 particles and they see what happens, right? 23 A Mm-hm. 24 Q Is that "yes"? 25 A Yes.</p>	<p style="text-align: right;">Page 293</p> <p>1 woman's reproductive tract, correct? 2 MS. PARFITT: Objection; form. 3 THE WITNESS: Again, it's the ethics 4 of applying something that could potentially be 5 carcinogenic to see what would occur. 6 Q (By Mr. Williams) Can you identify any study that shows 7 inflammation, granulomas, fibrosis, or adhesions anywhere 8 along a woman's reproductive tract as a result of her 9 external genital talcum powder application? 10 A I don't think I cited any such studies. 11 Q Can you identify any published animal study where talcum 12 powder actually caused ovarian cancer in the animal? 13 A There have been studies that showed that talc can lead to 14 cyst formation and epithelial changes in rats. 15 Q Which study is that? 16 A That is 122. 17 Hamilton. 18 Q Any other studies? 19 A Say that again? 20 Q You said "Hamilton," right? 21 A Hamilton, 1984. 22 Q Any other studies? 23 A Oh, and a mouse study, which is 123, Van Dyke. 24 Q 123? 25 A 123, yes, that talc can cause super NI generation and</p>

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<p>1 release from mouth to macrophages (phonetic).</p> <p>2 Q Anything else?</p> <p>3 A I am just looking.</p> <p>4 So you are talking about ovarian tumors.</p> <p>5 The NTP, the National Toxicology Program, has also</p> <p>6 done rat studies and found that exposure to talc cause--</p> <p>7 it was an inhalation study, caused clear evidence of</p> <p>8 carcinogenesis in females in terms of cancer of the</p> <p>9 adrenal gland and the lung and possible carcinogenic</p> <p>10 activity in males.</p> <p>11 Q What was the date of that NTP study?</p> <p>12 A NTP study? That was No. 124.</p> <p>13 1993.</p> <p>14 Q Are you familiar with the methodology of that study?</p> <p>15 A I have read the study, yes.</p> <p>16 Q And you know that the rats were subjected to talcum</p> <p>17 powder pumped into a cage-- a closed cage, I think it</p> <p>18 was, six hours a day, five days a week, for their entire</p> <p>19 lives, right?</p> <p>20 A Yes.</p> <p>21 Q Do you think that that has applicability to human beings</p> <p>22 using talcum powder in their homes?</p> <p>23 MS. PARFITT: Objection; form.</p> <p>24 THE WITNESS: Using talcum powder in--</p> <p>25 Q (By Mr. Williams) In their homes.</p>	<p>1 concluded that the 1993 rat study was not applicable or</p> <p>2 appropriate for application to humans?</p> <p>3 MS. PARFITT: Objection; misstates the</p> <p>4 evidence.</p> <p>5 Q (By Mr. Williams) I'm sorry, I misspoke.</p> <p>6 Are you aware that the FDA concluded that the 1993</p> <p>7 NTP study was not applicable to human beings?</p> <p>8 MS. PARFITT: Objection; misstates the</p> <p>9 evidence in the case.</p> <p>10 THE WITNESS: I would have to see both</p> <p>11 the FDA statement and the NTP.</p> <p>12 Q (By Mr. Williams) Can you identify-- strike that.</p> <p>13 I want to distinguish between a study, an animal</p> <p>14 study, where talcum powder caused inflammation on the one</p> <p>15 hand, with an animal study that found that talcum powder</p> <p>16 caused ovarian cancer.</p> <p>17 Do you have that distinction that I'm making in</p> <p>18 mind?</p> <p>19 Do you have the distinction I'm making in mind?</p> <p>20 A I'm just reading through my report.</p> <p>21 Q Inflammation on the one hand, ovarian cancer on the</p> <p>22 other.</p> <p>23 I am trying to make that distinction.</p> <p>24 Do you have that distinction in mind?</p> <p>25 When you say "yes," I'll ask you a question.</p>
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<p>1 A I think the correlation would be a larger concentrated</p> <p>2 dose being introduced into the genital tract, and if the</p> <p>3 talc is carcinogenic to animals and wasn't seen in the</p> <p>4 control animals, then it's still concerning.</p> <p>5 Q Did the 1993 NTP study in fact report any ovarian cancer</p> <p>6 in the female rats or mice?</p> <p>7 A I don't believe that these rats developed ovarian cancer.</p> <p>8 They did not develop ovarian cancer.</p> <p>9 Q Not one of them did, correct?</p> <p>10 A No.</p> <p>11 It may not be an ovarian cancer model.</p> <p>12 Q Did the 1993 NTP study report any neoplastic changes in</p> <p>13 the ovaries of the female rats or mice?</p> <p>14 A Not to my knowledge.</p> <p>15 Again, it's not a model for ovarian cancer.</p> <p>16 Q Can we agree that the NTP 1993 rat and mouse study does</p> <p>17 not in fact show that talc causes inflammation, which</p> <p>18 inflammation leads to neoplastic change or cancer in an</p> <p>19 animal's ovaries?</p> <p>20 MS. PARFITT: Objection; form.</p> <p>21 THE WITNESS: I don't have the study</p> <p>22 in front of me.</p> <p>23 I don't recall that they did the full mechanistic</p> <p>24 study.</p> <p>25 Q (By Mr. Williams) Do you recall that the NTP expressly</p>	<p>1 A So in Genofre's, G-E-N-O-F-R-E, study, in animal models,</p> <p>2 injection of talc into the pleura causes local and</p> <p>3 systemic inflammatory response, so it includes elevated</p> <p>4 levels of C-reactive protein and interleukin 6, and CEGF</p> <p>5 and TGF beta, and several of these are associated with</p> <p>6 increased risk of ovarian cancer in humans, including</p> <p>7 C-reactive protein and interleukin 8.</p> <p>8 Q Did that study that you are referring to, the Genofre,</p> <p>9 G-E-N-O-F-R-E, 2009 study, are you saying that that study</p> <p>10 showed that talc caused inflammation that led to</p> <p>11 neoplastic or cancerous changes in the animals?</p> <p>12 A This was a model looking at inflammation.</p> <p>13 Q And did that study show that talc application to the</p> <p>14 animal caused inflammation that led to cancerous changes?</p> <p>15 A To my knowledge, it stopped at the inflammatory response.</p> <p>16 Q None of the studies that you are relying upon -- Genofre</p> <p>17 -- compared C-reactive proteins, and that's C hyphen</p> <p>18 reactive proteins, or IL 8 levels between perineal talc</p> <p>19 users and nontalc users, correct?</p> <p>20 MS. PARFITT: Objection; form.</p> <p>21 THE WITNESS: I don't know about</p> <p>22 research that has looked at that.</p> <p>23 I do know that women with high levels of C-reactive</p> <p>24 protein or interleukin 8 are at an increased risk of</p> <p>25 developing ovarian cancer.</p>

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<p>1 Q (By Mr. Williams) None of the studies that you rely on</p> <p>2 concluded that C-reactive proteins or IL 8 levels can</p> <p>3 cause a local inflammatory response in the ovary,</p> <p>4 correct?</p> <p>5 MS. PARFITT: Objection; form.</p> <p>6 THE WITNESS: C-reactive protein and</p> <p>7 interleukin 8 are the inflammatory response.</p> <p>8 They are the products that are made during</p> <p>9 inflammatory response, to my knowledge.</p> <p>10 Q (By Mr. Williams) Was that an inflammatory response in</p> <p>11 the ovary?</p> <p>12 A It was blood-- the epidemiologic studies you are talking</p> <p>13 about was in blood.</p> <p>14 Q Can you identify any published study concluding that</p> <p>15 increased C-reactive protein levels leads to ovarian</p> <p>16 cancer in humans?</p> <p>17 A Yes, I have that.</p> <p>18 I am looking for it.</p> <p>19 I thought that I had reference to meta-analysis of</p> <p>20 C-reactive protein and risk of ovarian cancer, but it's</p> <p>21 not showing up.</p> <p>22 Q Can you identify any published study concluding that the</p> <p>23 C-reactive protein levels are greater in perineal talc</p> <p>24 users than nonperineal talc users?</p> <p>25 A I did not look at that.</p>	<p>1 Q Okay. That they, for a period of time, supplied the raw</p> <p>2 material talc to Johnson & Johnson for the baby powder.</p> <p>3 Are you aware of that?</p> <p>4 A I was aware that they did supply.</p> <p>5 I don't know anything about when or how much, no.</p> <p>6 Q Okay. So just a couple areas of questions:</p> <p>7 There were some questions that Mr. Williams asked</p> <p>8 you regarding chromium, nickel, and cobalt, and you said</p> <p>9 you do not know if those were contained in the Johnson &</p> <p>10 Johnson powder specifically.</p> <p>11 Do you recall that?</p> <p>12 A I do recall saying that.</p> <p>13 Q Okay. Same question as to Imerys.</p> <p>14 You do not know if Imerys raw talc specifically</p> <p>15 contained chromium, nickel, or cobalt, do you?</p> <p>16 A I would have to look.</p> <p>17 I know that the Pier deposition had some information</p> <p>18 at least about some of the talc.</p> <p>19 Do we have that?</p> <p>20 MS. PARFITT: Give us one moment.</p> <p>21 Do you want to have her identify--</p> <p>22 MS. ERFLE: Please do.</p> <p>23 THE WITNESS: So this is Exhibit</p> <p>24 No. 47 of Pier testimony, 9/13/18.</p> <p>25 Q (By Ms. Erfle) That's great. Let's look at that.</p>
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<p>1 Q Can you identify any published study concluding that the</p> <p>2 interleukin, and that's I-N-T-E-R-L-E-U-K-I-N, dash 8</p> <p>3 levels are greater in perineal talc users than</p> <p>4 nonperineal talc users?</p> <p>5 A I did not look at that.</p> <p>6 MR. WILLIAMS: That's all the</p> <p>7 questions I have, Doctor. Thank you very much.</p> <p>8 Let's go off the record.</p> <p>9 VIDEOGRAPHER: Going off the record,</p> <p>10 the time is 5:33 p.m. Please stand by.</p> <p>11 (Recess 5:33 to 5:35 p.m.)</p> <p>12</p> <p>13 VIDEOGRAPHER: We are back on the</p> <p>14 record. The time is 5:35 p.m.</p> <p>15</p> <p>16</p> <p>17 EXAMINATION</p> <p>18 BY MS. ERFLE:</p> <p>19 Q Dr. McTiernan, again, my name is Nancy Erfle. I</p> <p>20 represent Imerys Talc America, and you understand that's</p> <p>21 a different defendant than Johnson & Johnson, correct?</p> <p>22 A Yes, I do.</p> <p>23 Q And do you understand the role in this litigation, what</p> <p>24 their role is?</p> <p>25 A No. You can explain it.</p>	<p>1 So you have that in front of you?</p> <p>2 A Yes.</p> <p>3 Q And what about that indicates that there is chromium,</p> <p>4 nickel, or cobalt in the raw material specifically</p> <p>5 provided to Johnson & Johnson?</p> <p>6 A So these samples are all from Imerys--</p> <p>7 Q Do you know that to be the case?</p> <p>8 A That was my understanding, that that was the case, and I</p> <p>9 see Exhibit No. 38, chromium, cobalt, and nickel in a</p> <p>10 Johnson & Johnson sample.</p> <p>11 Q Okay. Do you know-- can you say-- how do you know that</p> <p>12 that's a J&J sample?</p> <p>13 A This is what is stated by the expert witness, to my</p> <p>14 understanding.</p> <p>15 Q So you've done no independent work yourself to confirm</p> <p>16 what these are or what these samples are, correct?</p> <p>17 A That's correct.</p> <p>18 I am relying on this testimony.</p> <p>19 Q So you don't know if these were actually samples that</p> <p>20 went into a Johnson & Johnson bottle that reached a</p> <p>21 consumer, correct?</p> <p>22 MS. PARFITT: Objection; form.</p> <p>23 Q (By Ms. Erfle) You can answer.</p> <p>24 A Correct.</p> <p>25 Q And you don't know if any of these items listed in</p>

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<p style="text-align: right;">Page 302</p> <p>1 Exhibit No. 47 of Ms. Pier's exhibit-- Exhibit No. 47 2 from Ms. Pier's prior testimony, if any of that actually 3 went to a competitor or was a competitor's product not 4 Imerys, correct? 5 MS. PARFITT: Objection; form. 6 THE WITNESS: Correct, I don't know 7 from this data. 8 Q (By Ms. Erfle) And you don't know from Exhibit No. 47 9 from Ms. Pier's prior deposition, that you are looking at 10 now, if any of that talc came from mines that were never 11 actually used for Johnson & Johnson product, correct? 12 MS. PARFITT: Objection; form. 13 THE WITNESS: Well, this does state 14 "Johnson & Johnson company" on two of the samples that 15 have chromium, cobalt, and nickel. 16 Q (By Ms. Erfle) But, again, you don't know if that 17 actually ever reached into a product that became body 18 powder from Johnson & Johnson that went to a consumer, 19 correct? 20 MS. PARFITT: Objection; form. 21 THE WITNESS: Correct. 22 (Exhibit No. 23 marked 23 for identification.) 24 Q (By Ms. Erfle) And just to make the record clear, let's 25 put in as Exhibit No. 23 the Julie Pier document that you</p>	<p style="text-align: right;">Page 304</p> <p>1 A It should be, yes. 2 (Exhibit No. 25 marked 3 for identification.) 4 5 Q (By Ms. Erfle) Let's mark as Exhibit No. 25 this-- can 6 you identify that for the record? 7 A This is a copy of my report with notes on it. 8 Yeah, it's a copy of my report, expert report, of 9 November 16th, 2018. 10 Q And it's the one with your handwritten notes? 11 A Yes. 12 Q Okay. One last question: 13 Do you have an invoice that you've generated from 14 December of 2018 through today, which is January 28th, 15 2019? 16 A Not yet. 17 Q Okay. And once you generate that invoice, will you 18 please give it to your counsel and make sure that they 19 provide it to us? 20 A Mm-hm. 21 Q Is that a "yes"? 22 A Yes. Yes. 23 MS. ERFLE: Okay. That's all I have. 24 MR. GOLOMB: How much time do you have 25 left--</p>
<p style="text-align: right;">Page 303</p> <p>1 are looking at, so we make sure it's a little clearer. 2 So all the questions I just asked you, 3 Dr. McTiernan, about the Julie Pier Exhibit No. 47, it's 4 also the same document as we've marked as Exhibit No. 23 5 to your deposition, correct? 6 A I can't read the whole thing, but it looks the same-- 7 it's the same number. 8 Q I will represent to you that that's another copy of it, 9 but it's marked as Exhibit No. 23 to this deposition, 10 okay? 11 A Okay. 12 Q Are you okay with that? 13 A Yes. 14 (Exhibit No. 24 marked 15 for identification.) 16 17 Q (By Ms. Erfle) Last thing I want to do is put in as 18 Exhibit No. 24-- Dr. McTiernan, can you please look at 19 that and identify that for the record, Exhibit No. 24? 20 A These are invoices that I submitted to Ms. Parfitt's firm 21 for work up until December 2018. 22 Q Okay. So let's mark as Exhibit No.-- and are those a 23 complete copy of all invoices that you would have 24 incurred from the time you began your work on this 25 litigation up until December of 2018?</p>	<p style="text-align: right;">Page 305</p> <p>1 MR. LOCKE: I don't think there's any 2 more time. 3 MR. GOLOMB: How much time is there on 4 that disc? 5 VIDEOGRAPHER: I have another like 15 6 minutes. 7 MS. PARFITT: Can we take a short 8 break, and we'll come back? 9 VIDEOGRAPHER: Okay. The time is 5:42 10 p.m. We are going off the record. 11 (Recess 5:42 to 5:50 p.m.) 12 13 VIDEOGRAPHER: We are back on the 14 record. The time is 5:50 p.m. This is Media Unit No. 5. 15 16 17 EXAMINATION 18 BY MS. PARFITT: 19 Q Dr. McTiernan, good evening. I just have a few questions 20 for you for the Ladies and Gentlemen of the Jury. 21 Dr. McTiernan, have you had an opportunity to review 22 the Canadian draft screening assessment by Health Canada? 23 A I did, yes. 24 Q And have you had an opportunity to review the entire 25 report?</p>

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<p style="text-align: right;">Page 306</p> <p>1 A Yes, I did.</p> <p>2 Q All right. And who sponsored that study?</p> <p>3 A It was Health Canada.</p> <p>4 (Exhibit No. 26 marked</p> <p>5 for identification.)</p> <p>6</p> <p>7 Q (By Ms. Parfitt) All right. I am going to have marked</p> <p>8 as Exhibit No. 26, Dr. McTiernan, a copy of just the</p> <p>9 draft screening assessment, dated December 2018, and,</p> <p>10 again, ask if you will identify that.</p> <p>11 A Yes, Exhibit No. 26.</p> <p>12 Q That is one of the documents you have reviewed?</p> <p>13 A Yes.</p> <p>14 Q Have you reviewed any other documents that are part of</p> <p>15 the Health Canada assessment of talc?</p> <p>16 A There was several other documents that were available.</p> <p>17 These were drafted by the Health Canada for</p> <p>18 information sheets for the public, and one that is called</p> <p>19 "Talc: potential risk of lung effects and ovarian</p> <p>20 cancer," another is a talc information sheet, a third is</p> <p>21 on talc, and, again it's also information for the public</p> <p>22 of how to minimize exposure, so they are already planning</p> <p>23 what the public health messages will be.</p> <p>24 One is a risk management scope, and this is to do</p> <p>25 with the regulatory decisions, and also the Canadian</p>	<p style="text-align: right;">Page 308</p> <p>1 talc can cause ovarian cancer.</p> <p>2 Q (By Ms. Parfitt) Specifically what are you referring to,</p> <p>3 if you will?</p> <p>4 A So on-- are there page numbers on here-- on Page 21 of</p> <p>5 the draft-- document called, "Draft screening</p> <p>6 assessment," in the fourth paragraph down, the third</p> <p>7 line, it says, "Further, available data are indicative of</p> <p>8 a causal effect."</p> <p>9 Another-- also, on Page 29, third paragraph down,</p> <p>10 states that "On the basis of information presented in</p> <p>11 this draft screening assessment, it is proposed to</p> <p>12 conclude that talc meets the criteria under Paragraph</p> <p>13 No. 64C of CEPA as it is entering or may enter the</p> <p>14 environment in a quantity or concentrations or under</p> <p>15 conditions that constitute or may constitute a danger in</p> <p>16 Canada to human life or health."</p> <p>17 Also in the beginning on Page Roman Numeral No. III,</p> <p>18 it states in the fifth paragraph, "The meta-analyses of</p> <p>19 the available human studies in the peer-reviewed</p> <p>20 literature indicate a consistent and statistically</p> <p>21 significant positive association between perineal</p> <p>22 exposure to talc and ovarian cancer. Further, available</p> <p>23 data are indicative of a causal effect."</p> <p>24 Q Dr. McTiernan, from reviewing the draft screening</p> <p>25 assessment performed by Health Canada, were you able to</p>
<p style="text-align: right;">Page 307</p> <p>1 weight of evidence general principles and current</p> <p>2 applications at Health Canada.</p> <p>3 Q Now--</p> <p>4 MR. LOCKE: Objection; nonresponsive,</p> <p>5 move to strike.</p> <p>6 Q (By Ms. Parfitt) Dr. McTiernan, the information from</p> <p>7 Health Canada was made available to you, I believe you</p> <p>8 testified, after your report was submitted in November</p> <p>9 2018; is that correct?</p> <p>10 A That's correct.</p> <p>11 Q All right. And the date, again, of the Health Canada</p> <p>12 assessment was December 2018, correct?</p> <p>13 A Yes, correct.</p> <p>14 Q So at the time you submitted your report in the</p> <p>15 multidistrict litigation, you did not have access to the</p> <p>16 Health Canada report, correct?</p> <p>17 A Correct.</p> <p>18 Q All right. Now, have you-- do you have an opinion, to a</p> <p>19 reasonable degree of scientific certainty, as to whether</p> <p>20 or not Health Canada has opined that talcum powder</p> <p>21 products can cause ovarian cancer?</p> <p>22 MR. WILLIAMS: Objection; lacks</p> <p>23 foundation, calls for speculation.</p> <p>24 THE WITNESS: Health Canada does, in</p> <p>25 several places, firmly state that talcum powder-- that</p>	<p style="text-align: right;">Page 309</p> <p>1 determine whether or not they did indeed perform a</p> <p>2 causality assessment?</p> <p>3 MR. WILLIAMS: Lacks foundation, calls</p> <p>4 for speculation.</p> <p>5 THE WITNESS: They did do a full</p> <p>6 causal analysis that includes information from</p> <p>7 toxicology, animal studies of the biologic information,</p> <p>8 perineal exposure to talc, and then the human studies.</p> <p>9 I am looking for where they did their full</p> <p>10 causation.</p> <p>11 So they then determined characteristic of risk to</p> <p>12 human health, and then came up with their conclusions</p> <p>13 about what-- that further available data are indicative</p> <p>14 of a causal effect.</p> <p>15 Q (By Ms. Parfitt) What methodology did they employ?</p> <p>16 A They did methodology that was similar to what I did for</p> <p>17 my report.</p> <p>18 They reviewed the epidemiologic data from a</p> <p>19 meta-analysis.</p> <p>20 They reviewed the data-- the literature on animal</p> <p>21 studies.</p> <p>22 They reviewed toxicology.</p> <p>23 They reviewed information in how talc can be-- can</p> <p>24 reach the ovary areas, and from that came up with their</p> <p>25 conclusions.</p>

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<p>1 Q Was part of the Health Canada causality assessment a 2 study by the name of Tair (phonetic)? 3 A Yes. That was the meta-analysis that they reviewed. 4 Q Okay. And that was just one part-- 5 A That was the primary meta-analyses-- the most recent 6 meta-analysis that I reviewed. 7 Q And that was just one part of the Health Canada 8 assessment; is that correct? 9 A Exactly. 10 Q Dr. McTiernan, you were asked by counsel for J&J whether 11 or not it would be repugnant for a company to test their 12 talcum powder products for asbestos. 13 Do you remember that question? 14 A I believe the question was posed-- I would have to review 15 the question again. 16 I believe there was something about brakes and 17 another-- 18 Q Let me just-- 19 A I think the category was talcum testing for asbestos. 20 Q I believe the question was whether-- first, whether it 21 was repugnant for a company to test for asbestos, whether 22 J&J would be repugnant for them to test-- to actually do 23 testing of their product. 24 Do you recall that? 25 A Yes.</p>	<p>1 VIDEOGRAPHER: This marks the end of 2 today's video deposition. The time is 5:59 p.m. 3 (Deposition concluded at 5:59 p.m.) 4 (Signature reserved.) 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>
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<p>1 Q And he then asked you whether it was repugnant if a brake 2 company also tested to determine whether or not their 3 products' brakes failed. 4 Do you remember that? 5 A Yes. 6 Q In your opinion would it be repugnant for a company, if 7 they found that the brakes had failed, to not inform the 8 public? 9 A Yes. 10 MR. WILLIAMS: Incomplete 11 hypothetical. 12 MR. LOCKE: Just note my objection. 13 Q (By Ms. Parfitt) Similarly, would it be repugnant of a 14 manufacturing company or a supplier who tested their 15 product and found asbestos to not warn or communicate 16 with the public and the medical and scientific field 17 about the fact that their product had asbestos? 18 MR. WILLIAMS: Same objection. 19 MS. ERFLE: Objection; also lacks 20 foundation. 21 THE WITNESS: Yes. 22 MS. PARFITT: I have no further 23 questions, Dr. McTiernan. Thank you. 24 MR. WILLIAMS: I think that's it-- 25 actually-- that's fine.</p>	<p>1 STATE OF WASHINGTON) I, Terilynn Simons, CCR, RMR, CRR 2) ss a certified court reporter 3 County of Pierce) in the State of Washington, do 4 hereby certify: 5 6 That the foregoing deposition of ANNE MCTIERNAN, PH.D. 7 was taken before me and completed on January 28, 2019, and 8 thereafter was transcribed under my direction; that the 9 deposition is a full, true and complete transcript of the 10 testimony of said witness, including all questions, answers, 11 objections, motions and exceptions; 12 That the witness, before examination, was by me duly 13 sworn to testify the truth, the whole truth, and nothing but 14 the truth, and that the witness reserved the right of 15 signature; 16 17 That I am not a relative, employee, attorney or counsel 18 of any party to this action or relative or employee of any 19 such attorney or counsel and that I am not financially 20 interested in the said action or the outcome thereof; 21 That I am herewith securely sealing the said deposition 22 and promptly delivering the same to Bart H. Williams. 23 24 IN WITNESS WHEREOF, I have hereunto set my signature on 25 the 30th day of January, 2019. Terilynn Simons, CCR, RMR, CRR Certified Court Reporter No. 2047 (Certification expires 07/07/19.)</p>

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<p>1 ----- E R R A T A 2 ----- 3 PAGE LINE CHANGE 4 _____ 5 REASON: _____ 6 _____ 7 REASON: _____ 8 _____ 9 REASON: _____ 10 _____ 11 REASON: _____ 12 _____ 13 REASON: _____ 14 _____ 15 REASON: _____ 16 _____ 17 REASON: _____ 18 _____ 19 REASON: _____ 20 _____ 21 REASON: _____ 22 _____ 23 REASON: _____ 24 _____ 25 REASON: _____</p>	
<p>1 ACKNOWLEDGMENT OF DEPONENT 2 3 I, _____, do 4 hereby certify that I have read the 5 foregoing pages, and that the same 6 is a correct transcription of the answers 7 given by me to the questions therein 8 propounded, except for the corrections or 9 changes in form or substance, if any, 10 noted in the attached Errata Sheet. 11 12 _____ 13 ANNE MCTIERNAN, PH.D. DATE 14 15 Subscribed and sworn 16 to before me this 17 _____ day of _____, 20____. 18 My commission expires: _____ 19 _____ 20 Notary Public 21 22 23 24 25</p>	

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Exhibit 19

Statement of Dr. Anne Mc Tiernan prepared for the Subcommittee on Economic and Consumer Policy Hearing on Examining the Public Health Risk on Carcinogens and Consumer Products, March 12, 2019

Chairman Krishnamoorthi, Ranking Member Cloud, and members of the subcommittee, good morning and thank you for inviting me. My name is Dr. Anne McTiernan. I am a cancer prevention researcher in the Epidemiology Program, Division of Public Health Sciences, at the Fred Hutchinson Cancer Research Center in Seattle, Washington. I am also a Research Professor in the University of Washington Schools of Public Health and Medicine. I am not representing the Fred Hutchinson Cancer Research Center or the University of Washington in the presentation of my testimony to the Subcommittee. I am an internal medicine physician and epidemiologist. My research focuses on cancer epidemiology and prevention, particularly cancers in women. I was asked to give testimony today because I have conducted a thorough and systematic review of the science linking use of talcum powder products and risk for ovarian cancer. As part of this review, I prepared an expert report on behalf of consumers for an ongoing multi-district litigation on talcum powder products as causes of ovarian cancer.

My scientific review focused primarily on the epidemiologic research. Epidemiologists look at large groups of people with a disease, and compare them to people without that disease, to find what might be causing the disease.

The American Cancer Society and the U.S. National Cancer Institute estimate that in 2019, 22,530 women will receive a new diagnosis of ovarian cancer and 13,980 women will die from ovarian cancer.(1, 2) There is no established method to screen for early ovarian cancer. As a result, most women are diagnosed at an advanced, less treatable stage. There is also no

established method to prevent ovarian cancer other than surgical removal of ovaries. Therefore, it is critical to identify causes of ovarian cancer in order to prevent this serious disease.

My review identified 38 high-quality epidemiologic studies conducted over the past 40 years.

These studies asked women about their use of talcum powder products in the genital area, and tested associations with risk of ovarian cancer. Together, these studies included over 14,000 women with epithelial ovarian cancer (the most common type) and an even greater number of women without ovarian cancer. Most of these studies were conducted in the United States.

Ovarian cancer is thought to develop over years. Therefore, a woman's exposures in her young and middle years can affect her risk of ovarian cancer decades later. Women have reported use of talcum powder products on sanitary napkins, underwear, and directly to the genital area. In some studies, over 4 in 10 women report ever regularly using these products in the genital area.(3)

Summarizing data from all of the published studies consistently shows that women who had ever used talcum powder products in the genital area had a statistically significant 22 - 31% increased risk of developing epithelial ovarian cancer compared with women who had never used them.(4-6) Evidence suggests that these associations hold across diverse race and ethnic groups.

These combined analyses showed that increasing amount of exposure to talcum powder products in the genital area resulted in increasing risk of developing epithelial ovarian cancer.

Published laboratory and clinical studies provide evidence that in humans, talc can migrate from the genital area to the ovaries and fallopian tubes. Talc has been shown to cause an

inflammatory response in the human body. Elevated levels of inflammation in women are associated with increased risk of ovarian cancer. All of this provides a biologically plausible pathway by which talcum powder product exposure can cause ovarian cancer.

Given the frequency with which asbestos has been found in cosmetic and personal use talc products, I reviewed the literature on the epidemiology of asbestos and risk of ovarian cancer. In 2012, the International Agency for Research on Cancer stated that a causal association between exposure to asbestos and cancer of the ovary was clearly established.⁽⁷⁾ That agency has also classified fibrous talc as a Class 1 carcinogen – the most dangerous level of carcinogen.

Given the high prevalence of use of talcum powder products, a 22 - 31% increase in risk can have profound effects on clinical events and public health. Women need to know about the risks of using talcum powder products in their genital areas. All consumers need to be warned about the contents of these products, including asbestos and fibrous talc, so that they can make informed decisions about use.

Thank you for the opportunity to provide this testimony. I would be happy to answer any questions you may have.

Anne McTiernan, MD, PhD

Full Member, Public Health Sciences

Fred Hutchinson Cancer Research Center, Seattle, Washington

1. <https://www.cancer.org/content/dam/CRC/PDF/Public/8773.00.pdf> (accessed 3/7/19)
2. Torre LA, Trabert B, DeSantis CE, Miller KD, Samimi G, Runowicz CD, et al. Ovarian cancer statistics, 2018. *CA: a cancer journal for clinicians*. 2018;68(4):284-96.
3. IARC. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 93. Carbon black, titanium dioxide, and talc*. Lyon, IARC (International Agency for Research on Cancer). 2010
4. Berge W, Mundt K, Luu H, Boffetta P. Genital use of talc and risk of ovarian cancer: a meta-analysis. *Eur J Cancer Prev*. 2017.
5. Penninkilampi R, Eslick GD. Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis. *Epidemiology*. 2018;29(1):41-9.
6. Terry KL, Karageorgi S, Shvetsov YB, Merritt MA, Lurie G, Thompson PJ, et al. Genital powder use and risk of ovarian cancer: a pooled analysis of 8,525 cases and 9,859 controls. *Cancer prevention research (Philadelphia, Pa)*. 2013;6(8):811-21.
7. IARC - Monograph Vol. 100C - Arsenic, Metals Fibres, and Dusts: A review of human carcinogens. Lyon, International Agency for Research on Cancer/World Health Organization. 2012

Exhibit 20

From: [McTiernan, Anne](#)
To: eccc.substances.eccc@canada.ca
Bcc: [McTiernan, Anne](#)
Subject: comment on Canada Gazette Part 1 December 8, 2018
Date: Tuesday, February 5, 2019 5:36:00 PM

Executive Director,
Program Development and Engagement Division
Department of the Environment
Gatineau Quebec K1A 0H3

Dear Sirs/Madams:

Re: Draft Screening Assessment – Talc; Chemical Abstracts Service Registry Number
14807-96-6, published in Canada Gazette, Part 1, December 8, 2018

Health Canada has performed an excellent assessment of the state of science regarding the role of use of talcum powder products and risk of ovarian cancer. The Draft Screening Assessment on Talc presents information on research in humans, animals, cells, as well as toxicological and pathological research. The assessment states, “The meta-analyses of the available human studies in the peer-reviewed literature indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer. Further, available data are indicative of a causal effect.” The assessment concludes, “Based on the available information, it is proposed that there is potential for harm to human health in Canada at current levels of exposure. Therefore, on the basis of the information presented in this draft screening assessment, it is proposed to conclude that talc meets the criteria under paragraph 64(c) of CEPA as it is entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.”

This conclusion agrees with my own: I conducted a systematic review and causation analysis of the association between use of talcum powder products in the genital/perineal area and risk of developing epithelial ovarian cancer. There have been 33 scientific publications from epidemiologic studies, as well as a pooled analysis and several meta-analyses that combined data across multiple studies. The meta-analyses consistently showed that women who have ever used talcum powder products in the genital/perineal area have a statistically significant 22 - 31% increased risk of developing epithelial ovarian cancer overall compared with women who reported never using these products. These comprehensive combined analyses also show strong evidence of increased risk of ovarian cancer with increasing number of estimated lifetime applications of talcum powder products in the perineal/genital area.

Laboratory and clinical studies on talc exposure and ovarian carcinogenesis have provided plausible evidence that talc can migrate from the perineum to the ovaries and that it can cause an inflammatory response. Elevated levels of inflammation (such as cytokines), as well as oxidative stress, are biologically plausible pathways by which talc can induce neoplastic change and cause ovarian cancer.

Given that use of talcum powder products in the genital/perineal area can cause ovarian cancer, Health Canada is right in taking the proposed actions to reduce exposure to these products in order to protect the health of Canadian women.

Sincerely,

Anne McTiernan, MD, PhD
Member, Division of Public Health Sciences
Fred Hutchinson Cancer Research Center
Research Professor, Schools of Public Health and Medicine
University of Washington
Seattle, WA, USA

Disclosure: Dr. McTiernan has received consulting funds from legal firms representing plaintiffs in cases of ovarian cancer and talcum powder products.

Exhibit 21

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON TALCUM
POWDER PRODUCTS MARKETING,
SALES PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

**Civil Action No. 3:16-md-
2738-FLW-LHG**

MDL No. 2738

***THIS DOCUMENT RELATES TO ALL
CASES***

AFFIDAVIT OF ANNE MCTIERNAN, MD, PHD

I, Anne McTiernan, do hereby declare as follows:

1. I am over the age of 18 years of age and otherwise competent to testify to the matters contained in this affidavit.
2. I have been retained by the Plaintiffs in this case as an expert witness.
3. I have reviewed Defendants' Memorandum of Law in Support of Motion to Exclude Plaintiffs' Experts' General Causation Opinions which cites to and draws inferences from a recent World Cancer Research Fund (WCRF) and American Institute for Cancer Research (AICR) publication I contributed to.
4. Defendants misinterpret this publication, which should not be cited as a comprehensive authority on known risk factors for ovarian cancer.
5. The following are my responses to these and related inferences drawn by Defendants in citing the Third Expert Report. My failure to address any other points made by Defendant's in their motions to exclude my testimony and opinions should not be interpreted as an expression of agreement with such point(s). All statements of fact are true and correct, and all opinions are based on, amongst other things, my training, experience, research, and involvement with the WCRF and AICR.
6. **In light of the foregoing, the following are my responses:**
7. Defendants call attention to a recent report by the WCRF and AICR, which did not identify talc as a risk factor for ovarian cancer, in an attempt to

demonstrate a current lack of scientific support for a causal link between ovarian cancer and talcum powder products. World Cancer Res. Fund Int'l Continuous Update Project, *Diet, Nutrition, Physical Activity and Ovarian Cancer* (revised 2018) (subpart of overall "Third Expert Report" described below).

8. Defendants also emphasize my work on the panel responsible for evaluating this report to suggest that our panel did not consider talc a risk factor for ovarian cancer and consequently made an affirmative decision to not list talc as a risk factor in this report.
9. These portrayals seek to discredit the body of scientific literature supporting a causal association between use of talcum powder products and risk of ovarian cancer and to discredit my opinions in this case by suggesting they are inconsistent with my past work on ovarian cancer research.
10. These portrayals of the report and the work of the panel, including my own involvement, are incorrect for two primary reasons.
11. **First**, Defendants misunderstand the purpose of this report and the process by which it was generated. Contrary to their assertion, it should not be cited as a recent evaluation or listing of known risk factors for ovarian cancer. Instead, the report focuses solely on healthy lifestyle factors related to cancer, specifically diet, exercise, and nutrition.
12. The report Defendant's cite stems from the WCRF and AICR's Continuous Update Project (CUP), an ongoing program to analyze cancer prevention and survival research related to diet, nutrition and physical activity. For the past several decades, this project has periodically released updated reports on cancers which may be affected by diet and exercise. Approximately every 10 to 12 years, these cancer-specific reports are compiled into overall "Expert Reports." The First Expert Report was published in 1997 and the Second Expert Report was published in 2007.
13. The recent 2018 publication is designated the "Third Expert Report." Third Expert Report, *Diet, Nutrition, Physical Activity and Cancer: A Global Perspective* (2018) ("Third Expert Report"). The Third Expert Report includes eighteen separate reports on specific cancer sites. In preparing for the publication of the Third Expert Report, only three of these reports were evaluated and updated on a small number of select nutritional variables: endometrial, pancreatic, and stomach cancers.

14. The specific 2018 revision report Defendants cite to is the ovarian-specific report contained within the Third Expert Report. That report was not substantively updated or reevaluated for the 2018 publication because it had recently been updated in 2014. As it stands, the 2018 revision cited here is a near-verbatim copy of the 2014 ovarian-specific report which was updated from an earlier version prepared for the 2007 Second Expert Report.
15. Between the earlier 2014 report and the present 2018 revision cited, there have been no changes to the substantive data, associations or risk estimates, panel conclusions, or panel judgements.
16. The ultimate summaries and conclusions reached in the report are specifically based on data for diet, nutrition, and exercise, and do not consider other ovarian cancer risk factors.
17. These summaries and conclusions were reviewed generally by myself and other members of the panel prior to publication during a June 2017 CUP Panel Meeting. To be clear, the review here was cursory because the Ovarian Cancer report had recently been updated in 2014 and was not a focus for updating for the overall 2018 Third Expert Report.
18. The 2018 revision updated general text and information about the WCRF and AICR, and minor changes to synchronize the ovarian-specific report for the overall Third Expert Report refresh from the earlier 2007 Second Expert Report. The following are a few examples of these synchronizations in the 2018 revision of the ovarian-specific report:
 - a. Updated "About WCRF and the CUP" boilerplate language.
 - b. Updated "How to cite" the Third Expert Report and the ovarian-specific report.
 - c. Updated cover with phrase "Revised 2018" in place of "2014" and changed style of cover to match Third Expert Report.
 - d. Updated internal signposts on how to refer to and cite the Third Expert Report.
 - e. Added a paragraph in the mechanistic evidence section referring back to the Third Expert Report and noting that the Third Expert Report discussion of mechanistic evidence are not based on a systematic or exhaustive search of the literature.

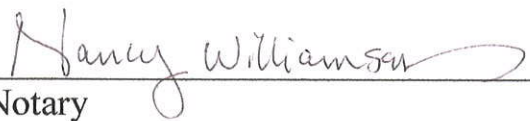
- f. Added a back cover which mirrors the diet and nutrition recommendations listed on the inside back cover of the overall Third Expert Report.
 - g. Updated cover to stylistically match overall report and include the AICR twitter handle.
19. While the cited 2018 revision report includes two short paragraphs referencing “other established causes,” and Defendants may attempt to cite this as up-to-date and comprehensive, I want to make clear that this section does not include all known risk factors. Additionally, the language and content of these paragraphs is a verbatim copy of the text from the 2014 updated ovarian-specific report and was not updated or reevaluated for the 2018 revision.
20. Based on these additional details, it should be clear that any reference to this report outside the healthy lifestyle context of diet, nutrition, physical activity, or as an updated and comprehensive summary of known ovarian cancer risk factors, would be an incorrect and unreliable.
21. **Second,** and based upon the improper inference discussed above regarding the non-comprehensive nature of this report, Defendants suggest this report conflicts with my opinions generally and expressed in this case that there is a causal association between ovarian cancer and talcum powder products.
22. To be clear, the 2018 revised report was developed and finalized by the CUP panel I serve on before I began my work as an expert in this case.
23. While the report was formally published shortly after my retention, that administrative process is completely unrelated and detached from my work on the CUP panel.
24. And, as detailed above, the Third Expert Report only made substantive updates to the underlying reports on endometrial, pancreatic, and stomach cancers. For that reason, the CUP panel discussions on the Third Expert Report would not have been the correct forum to discuss causal evidence on cancers that were not being substantively reviewed.
25. To reiterate and conclude, I believe it would be inaccurate and incorrect to cite the 2018 revision of the 2014 report on ovarian cancer as a comprehensive authority on risk factors for ovarian cancer. The report is non-comprehensive, is focused solely on healthy lifestyle (diet, nutrition,

physical activity), and has not been reviewed for substantive updates for more than five years.

FURTHER AFFIANT SAYETH NOT.


ANNE MCTIERNAN, M.D., PH.D.

SWORN AND SUBSCRIBED TO before me this 28th day of May 2019:


Notary

State of Washington

County of King

My Commission expires 06/26/2021

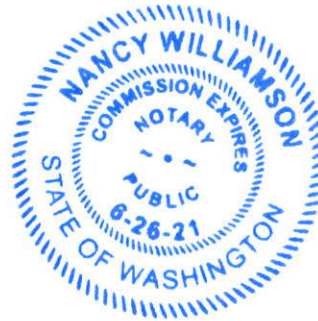


Exhibit 22

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

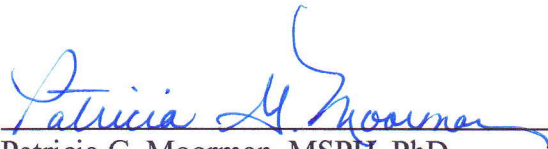
IN RE JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES,
AND PRODUCTS LIABILITY
LITIGATION

MDL NO. 16-2738 (FLW) (LHG)

THIS DOCUMENT RELATES TO ALL CASES

RULE 26 EXPERT REPORT OF
PATRICIA G. MOORMAN, MSPH, PHD

Date: November 16, 2018


Patricia G. Moorman, MSPH, PhD

Scientific Review of the Epidemiologic Evidence on Talc Use and Ovarian Cancer

Patricia G. Moorman, MSPH, PhD

Professor, Department of Community and Family Medicine
Cancer Control and Population Sciences, Duke Cancer Institute
Duke University School of Medicine
Durham, NC

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Background and Qualifications of Patricia G. Moorman, MSPH, PhD

I am a tenured professor in the Department of Community and Family Medicine, Duke University School of Medicine, Durham, NC and a member of the Cancer Control and Population Sciences Program in the Duke Cancer Institute. I am an epidemiologist with more than 25 years of experience in conducting research on women's health issues including ovarian cancer, breast cancer and menopause. Attached as Exhibit A to this report is a current copy of my curriculum vitae.

Education

I received a Bachelor of Science degree with distinction in pharmacy from the University of Kansas in 1980. I pursued graduate studies in epidemiology in the School of Public Health at the University of North Carolina-Chapel Hill, earning a Master of Science in Public Health (MSPH) in 1989 and a Doctor of Philosophy (PhD) degree in 1993.

Professional Experience

I have held positions in academic institutions since I completed my PhD, beginning as a research assistant professor in the Department of Epidemiology at the University of North Carolina-Chapel Hill from 1994 through 1996. From 1997 to 2000, I was an associate research scientist in the Chronic Disease Epidemiology division of the Yale University School of Public Health. I came to Duke University School of Medicine as an assistant professor in 2000, progressing through the academic ranks from associate professor, associate professor with tenure to my current position as professor in Community and Family Medicine. I also serve as the director of the Clinical Research Unit for the Department of Community Medicine and am a member of the Senior Faculty Advisory Committee for the Office for Research Mentoring in the School of Medicine. In addition, I am an adjunct faculty member in the Department of Epidemiology at the University of North Carolina-Chapel Hill.

Compensation and Testimony

My hourly billing is \$400. I have given deposition testimony in one case (Gail Ingham, et al., v. Johnson & Johnson, et al., Case No. 1522-CC10417-01, Circuit Court of the City of St. Louis, Division 10) and have not testified at trial in the last four years.

Research Interests and Experience

My primary research interests are in the area of women's health issues, with a particular focus on studying racial differences in risk factors and outcomes. I have had funding from the National Institutes of Health (NIH) for more than 20 years, which has supported my research in ovarian cancer, breast cancer and ovarian function after hysterectomy. Three of the key studies in my research career are: 1) the African American Cancer Epidemiology Study (AACES), a multi-center, case-control study of ovarian cancer in African American women,¹ 2) the Carolina Breast Cancer Study, which is one of the largest studies focused on understanding racial differences in breast cancer risk and outcomes,² and 3) the Prospective Research on Ovarian Function (PROOF) Study, a cohort study designed to examine risk for ovarian failure after premenopausal hysterectomy.³

Each of these studies involved primary data collection, meaning that the investigative team designed the data collection procedures, developed the surveys, recruited study participants and obtained questionnaire data and biological specimens from the participating women. Each study has made unique contributions to the scientific literature.

AACES has enrolled more than four times as many African-American women with ovarian cancer than any other study and is providing the most comprehensive epidemiologic data on ovarian cancer risk factors in this population to date.⁴⁻⁶ The Carolina Breast Cancer Study likewise provided key data on risk factors in African American women and was the first study to describe the markedly higher prevalence of the poor-prognosis basal subtype of breast cancer in young African American women.⁷⁻¹¹ The PROOF study is the largest prospective study of ovarian function after pre-menopausal hysterectomy and demonstrated that women

undergoing hysterectomy with ovarian conservation were at significantly increased risk for earlier menopause as compared to women who did not have a hysterectomy.^{3,12}

Our study team published an analysis of talc exposure and ovarian cancer in 2016, using data from AACES.¹³ This peer-reviewed paper, published in *Cancer Epidemiology, Biomarkers and Prevention*, was the first epidemiologic study of talc use and ovarian cancer that was focused exclusively on African American women. Our analyses found both a high prevalence of talc use in this study population and a statistically significantly increased risk for ovarian cancer among talc users. This paper was published prior to my involvement in litigation related to talc and ovarian cancer.

I have also been a co-investigator on the North Carolina Ovarian Cancer Study, which was a precursor to the AACES study. Data from this study were included in Terry, et al.'s¹⁴ 2013 analysis of genital powder use and ovarian cancer that pooled from data from eight case-control studies. I am currently an investigator in the Ovarian Cancer in Women of African Ancestry (OCWAA) consortium. The OCWAA consortium, which was initiated in 2016, is a multi-center collaboration that aims to bring together data from case-control and cohort studies to evaluate similarities and differences between African American and white women in ovarian cancer risk factors and outcomes.

In addition to these studies, I am an investigator with the Evidence Synthesis Group in the Duke Clinical Research Institute, a team of researchers that conducts evidence reviews of the scientific literature. I have worked with this group on a number of systematic reviews and meta-analyses on women's health issues including an evaluation of the benefits and risks of oral contraceptive use for primary prevention of ovarian cancer¹⁵⁻¹⁷ funded by the Agency for Healthcare Research Quality, and an evaluation of the benefits and harms of breast cancer screening¹⁸ funded by the American Cancer Society to help inform their screening mammography recommendations.¹⁹

I am an author on more than 130 scientific publications, with more than 50 of them directly related to ovarian cancer. The ovarian cancer papers address a wide variety of risk factors including reproductive and hormonal factors, lifestyle characteristics, genetic factors, and talcum powder products. The main focus of the manuscripts on which I have been the lead

author has been ovarian cancer risk factors in African American women and the effects of reproductive characteristics, hormones and other medications on risk for ovarian cancer.^{5,17,20-}

²³ The papers have been published in some of the leading journals in the field of epidemiology, gynecology and cancer including the *American Journal of Epidemiology*, *Cancer Epidemiology Biomarkers and Prevention*, *Obstetrics & Gynecology* and *Journal of Clinical Oncology*.

My teaching experience includes courses in Cancer Epidemiology for graduate students in public health and Evidence-Based Medicine for physician assistant students. A primary emphasis of these courses has been for the students to gain an understanding of the advantages and disadvantages of different types of studies used in clinical and epidemiologic research. In particular, the Evidence-Based Medicine course is designed to help the students learn how to critically appraise the medical literature and apply findings to clinical practice. In addition, I have mentored at the individual level public health graduate students and medical students.

I serve as an editorial reviewer for numerous journals and have served as a peer reviewer of grant applications on several dozen study sections over that past twenty years. I have reviewed NIH grants for a variety of funding mechanisms ranging from small grants (R03) to large multi-project applications (SPORE grants and Program Projects). I also have served as both peer reviewer and study section chair for the Susan G. Komen for the Cure Foundation and the Department of Defense Ovarian Cancer and Breast Cancer Research Programs.

In summary, in a career spanning more than 25 years, I have devoted my efforts to understanding factors that affect risk for ovarian cancer, breast cancer and menopause. I have conducted original research, giving me a deep appreciation of the advantages and disadvantages of different study designs and the challenges of collecting high-quality data for making etiologic inferences. I also have conducted research involving synthesis of the published literature, with the goal of informing decisions based on the best available evidence. A large proportion of my publications have focused on the epidemiology of ovarian cancer, and many of the others focused on breast cancer or menopause have relevance to ovarian cancer because of shared risk factors for the conditions. Based on my education, experience, and expertise, I

am highly qualified to assess the literature on the use of talc in relation to ovarian cancer and provide an expert opinion to a reasonable degree of medical certainty.

Purpose

The purpose of this report is to summarize the epidemiologic evidence related to talc use and ovarian cancer risk and to make a judgment as to whether there is sufficient evidence, based on the totality of evidence from epidemiologic investigations as well as laboratory and mechanistic studies, to conclude with a reasonable degree of scientific certainty that talcum powder use is a causal factor for ovarian cancer.

Throughout the report, the term "talc" will be used to refer to talcum powder products, recognizing that commercial talc products can contain asbestos, talc containing asbestiform fibers (e.g., talc occurring in a fibrous habit), heavy metals such as nickel, chromium and cobalt and fragrances.

Role and Importance of Epidemiologic Studies

It is important to bear in mind that epidemiologic research on factors that are thought to increase risk for cancer in human populations will consist of observational rather than experimental studies. As with most other now-known carcinogens, including cigarette smoke, it is both ethically wrong and pragmatically impossible to conduct randomized controlled trials to investigate whether a given exposure increases risk for cancer in humans. The judgment as to whether talc causes ovarian cancer will be based on epidemiologic studies in which the investigators collected and analyzed information on exposures (i.e., talc use and other risk factors) that the study participants chose to use, rather than studies in which exposures were randomly assigned to the study subjects in an experimental setting.

Observational study designs used in the study of talc and ovarian cancer include cohort and case-control studies, both of which are well-established and generally accepted methods for studying cancer etiology. In a prospective cohort study, a large group of individuals (the cohort) is identified and exposure to various factors hypothesized to affect risk of disease is

assessed at the time of enrollment (baseline). The cohort is followed over time and the analyses focus on whether the exposed group is more or less likely to develop the outcome of interest than the unexposed group. Some of the prominent advantages of cohort studies are that multiple outcomes/diseases can be assessed within the cohort and exposure assessment precedes the development of the disease, limiting recall bias. However, a primary disadvantage of cohort studies, particularly in relation to cancer etiology studies, is that they must enroll tens of thousands of subjects and follow them for long periods of time to accrue enough cases to have a well-powered study. In addition, if cohort studies do not update exposure information after the baseline assessment, the exposure of some individuals in the cohort may be misclassified.

Case-control studies identify individuals with the disease of interest and an appropriate control group of individuals without the disease and assess exposures that are thought to increase or decrease the risk of the disease. The investigators then analyze whether cases are more likely than the controls to have a given exposure. Case-control studies focus on a single disease, therefore they typically collect more detailed risk factor information for that disease than cohort studies. A major advantage of case-control studies is that they are a more efficient design for studying diseases that are less common or have a long latency period. Therefore, they are very commonly used for etiologic studies of cancer. A disadvantage of case-control studies is that they collect exposure information for the cases after they have already been diagnosed with the disease, which raises concerns that cases may recall exposures differently from controls.

Cohort studies and case-control studies each have advantages and disadvantages for assessing talc as a risk factor for ovarian cancer, and one study design is not clearly superior to the other. In addition, specific details related to the conduct of the study such as methods of exposure assessment, length of follow-up and choice of control group can impact the validity of the findings and the interpretation of results. Therefore, rather than making a judgment based only on the overall study design, the evaluation and interpretation of the findings of the studies must consider the strengths and weaknesses of the individual studies. As the results of the

studies are described and evaluated in this report, specific advantages and disadvantages of individual studies will be discussed in more detail.

In contrast to studies on laboratory animals, studies on humans are subject to more variation in exposure assessment and it is impossible to control all other factors that may contribute to disease risk. For these reasons, judgments on causality from epidemiologic research typically are not based on a single study or even a few studies, but are based on the totality of evidence from multiple studies conducted in different study populations, in different locations and across different time periods. Evidence from the epidemiologic investigations is combined with relevant studies from other disciplines, including pathology, animal and mechanistic studies, to make an assessment of the evidence for a causal association between genital exposure to talcum powder and ovarian cancer.

Methodology

The methodology I used to assess the epidemiologic evidence on talc use as a causal risk factor for ovarian cancer involved conducting a literature search on PubMed using the terms “ovarian cancer” and “talc” to identify all relevant original studies, systematic reviews, meta-analyses, editorials and commentaries (search most recently updated on October 29, 2018). The search I did returned 131 articles, all of which were systematically considered and assessed as to their relevance to talc as a risk factor for ovarian cancer. Twenty-nine articles were not directly relevant to the question at hand (mostly addressing talc in the treatment of malignant pleural effusions). Of the remaining 101 articles, 36 were reports of original epidemiologic studies directly addressing genital talc exposure and ovarian cancer or meta-analyses of such studies.^{14,24-56} Other articles retrieved included studies of occupational talc exposure,⁵⁷⁻⁶² other original research articles that were not specifically epidemiologic studies of genital talc and ovarian cancer (e.g., studies of endometrial cancer, pathology studies, animal studies, etc.)⁶³⁻⁸⁰ and reviews, commentaries and letters^{60,81-120} I also examined reference lists from key articles to identify any additional relevant studies. In addition, I reviewed relevant studies as well as documents provided during the course of discovery process.

The primary focus of my review is the epidemiologic studies of genital talc exposure and ovarian cancer and the meta-analyses, with supporting information from other types of publications, including animal, pathology and mechanistic studies used as appropriate to address biological mechanisms underlying the association between talc use and ovarian cancer.

As I evaluated the individual epidemiologic studies (case-control and cohort studies) that described the risk for ovarian cancer associated with talc use, I did not weight one design more heavily than the other because there are advantages and disadvantages to each design for evaluating talc as a cause of ovarian cancer. I considered the potential biases of individual studies, both those that supported and those that did not support an association between talc and ovarian cancer, and how those biases may have impacted the findings. As I describe in this report, some biases have the potential to lead to an overestimate of the relative risk (e.g. recall bias in case-control studies) while others could result in an underestimate of the relative risk (e.g. incomplete ascertainment of talc use in the cohort studies).

I also considered the studies that combined data from multiple studies – meta-analyses or pooled analyses from multiple case-control studies. These types of analyses are often considered to be some of the strongest evidence for a causal association between an exposure and disease as they provide an estimate of the relative risk that is more statistically robust than individual studies. Data from meta-analyses are particularly important for evaluating exposure-disease relationships such as talc and ovarian cancer where the relative risks from most individual studies are approximately 1.2 to 1.5.

As is standard in epidemiologic research, my assessment of whether there is a causal association between talc use and ovarian cancer was guided by the aspects of a causal relationship described by Bradford Hill during the 1960's. Sir Austin Bradford Hill's writings on causal inference provide an accepted framework for assessing whether a given exposure is a cause of a specific outcome.¹²¹ The aspects of the associations that Hill described are: Strength, Consistency, Specificity, Temporality, Biological Gradient, Plausibility, Coherence, Experiment and Analogy. As his writings clearly state, these viewpoints or perspectives should be taken into account when assessing causality, but are not to be considered absolute criteria and not all must be checked off to make a conclusion of a causal relationship. Specifically, he states "What

I do not believe is that we can usefully lay down some hard-and-fast rules of evidence that must be obeyed before we accept cause and effect. None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine qua non*.” This list of viewpoints was used to guide my assessment of the scientific literature on talc use and ovarian cancer.

It is important to point out that, in the end of this process, the assessment of whether a substance is or is not a causal risk factor for a given disease or condition involves scientific judgment that is made by considering and weighing the evidence. In any given case, it is not unusual for scientists and epidemiologists to weigh the Hill factors differently in reaching a conclusion on the causal inference in question. For example, scientists for many years debated the evidence that cigarette smoking causes lung cancer or asbestos causes lung disease.

Epidemiologic Studies Reviewed

Since 1982, when the first case-control study describing an increased risk for ovarian cancer associated with talc use was reported by Cramer, et al.,⁵⁰ more than two dozen additional reports of epidemiologic studies have been published.^{13,14,24-36,38-44,46-49,51-55,122,123} In some instances, data from a particular study were included in more than one publication, due either to an additional analysis of data from a cohort study with longer duration of follow-up (e.g.,^{31,34}) or to analyses that combined data from more than one study (e.g.,^{14,25}). Included in these publications are seven meta-analyses published between 1992 and 2018 that combined overall results from nine to 27 studies^{35,51,52,54-56} and a pooled analysis published in 2013 that combined individual level data from eight case-control studies.¹⁴

Strength and Consistency of the Association

The first two aspects of the causal relationship described by Bradford Hill, strength and consistency of association, are deeply intertwined. While Bradford Hill referenced the assumption that a larger relative risk is more likely to reflect a causal association, Hill also clearly stated that we should not be “too quick to dismiss a cause-and-effect hypothesis merely

on the grounds that the observed association appears to be slight. There are many occasions in medicine when this is in truth so.”¹²¹

Seven meta-analyses of genital talc exposure and ovarian cancer^{35,44,51,52,54-56} calculated summary relative risks that were very consistent across the publications, ranging from 1.22 to 1.36, all with 95% confidence intervals excluding 1, indicating that women who reported talc use were at statistically significant increased risk for ovarian cancer. Similarly, the pooled analysis of eight case-control studies reported an overall odds ratio of 1.24 (95% confidence interval (CI) 1.15 – 1.33).¹⁴

To put this in context, it is useful to compare the epidemiologic data related to the strength of the association between genital talc use and ovarian cancer with some other well-accepted exposure-disease associations that have relative risks of similar magnitude and are generally accepted to be causal associations. Some examples of such associations and the relative risks from these exposures estimated from meta-analyses are:

1. Oral contraceptive use and breast cancer, relative risk 1.08 (95% CI 1.003-1.165) for ever versus never use and relative risk 1.21 (95% CI 1.04-1.41) for current or recent use versus never use¹⁶
2. Menopausal estrogen use and breast cancer, relative risk 1.20 (95% CI 1.06-1.37) for more than 5 years use versus no use¹²⁴
3. Passive smoking (also referred to as environmental tobacco exposure or secondhand smoke) and lung cancer, relative risk 1.27 (95% CI 1.17-1.37) for ever versus never exposure to a spouse who smoked¹²⁵
4. Residential radon exposure and lung cancer, relative risk 1.29 (95% CI 1.10-1.51) for highest versus lowest exposure¹²⁶
5. Trichloroethylene exposure and kidney cancer, relative risk 1.32 (95% CI 1.17-1.50) for occupational exposure.¹²⁷

Each of these exposure/disease associations is widely accepted as a causal relationship in the scientific community and has been judged to be a causal association by the International Agency for Research on Cancer (IARC).^{128-130 131} The estimates of the relative risks for these associations from meta-analyses or pooled analyses are approximately 1.25,^{16,124-126,132,133}

which is in the range of estimates of the relative risk from meta-analyses and pooled analyses for the association between genital talc use and ovarian cancer. Therefore, we have evidence of well-established causal associations in which the magnitude of the relative risk is very similar to what has been reported for genital talc use and ovarian cancer.

It is instructive to compare in more detail the epidemiologic data on passive smoke exposure to that of talc and ovarian cancer. Passive smoke exposure, like talc, is a very common exposure in the population that can only be assessed retrospectively through self-report, therefore it is difficult to determine the precise level of exposure. In a meta-analysis of 55 studies published between 1981 and 2006 that examined the risk for lung cancer in never smoking women with passive smoke exposure from their spouses, Taylor, et al.¹²⁵ reported a pooled relative risk of 1.27 (95% CI 1.17-1.37). The relative risks from individual studies ranged from 0.66 to 2.57, with 44 of the 55 (80%) individual studies reporting a relative risk or odds ratio >1. In the individual studies, only 10 of 55 (18%) reported statistically significant associations (2 of 7 cohort studies, 3 of 25 case-control studies with population-based controls and 5 of 23 case-control studies). These data show that among the many epidemiologic studies that assessed passive smoke exposure as a risk factor for lung cancer, not all had statistically significant findings and some even reported relative risks less than one, yet the overall conclusion from the totality of the evidence is that passive smoke exposure is causally associated with lung cancer.

The most recent meta-analysis published in 2018 on talc and ovarian cancer by Pennikilampi et al. reported a pooled relative risk of 1.31 (95% CI 1.24-1.39) with values from individual studies ranging from 0.73 to 3.90.⁵⁶ This result is consistent with other meta-analyses performed. Twenty-four of the 26 (92%) studies reported a relative risk or odds ratio >1, and statistically significant associations were reported in 14 of the 26 (54%) studies. This comparison illustrates that as compared to the well-established causal association between passive smoke exposure and lung cancer, the association between talc and ovarian cancer has a pooled relative risk estimate of similar magnitude with a greater proportion of the studies reporting relative risks >1 and a greater proportion reporting statistically significant

associations suggesting the evidence for talc and ovarian cancer is as significant as for passive smoke exposure and lung cancer.

These comparisons also illustrate the importance of meta-analyses in epidemiologic research when considering exposures for which the strength of association is approximately 1.5 or less. Individual studies, especially those with smaller samples sizes, may not detect a statistically significant increased risk. When the increased risks in this range are seen repeatedly, even when individual studies are not statistically significant, meta-analysis allows the data to be aggregated to make a conclusion that is more robust statistically. When combining these studies through meta-analysis, the totality of the data shows that there is indeed a statistically significant link between genital talc use and ovarian cancer. This observation has been quite consistent, with findings replicated in studies conducted by different teams of investigators, in different geographic locations within and outside the United States, in different race/ethnic groups and over a span of several decades.

In conjunction with the strength of the association, it is also critical to consider the prevalence of the exposure in the population when evaluating its public health impact. A risk factor that is less strongly associated with a disease but has a high prevalence in the population can be responsible for more cases of the disease than a risk factor that is more strongly associated with the disease but has a low prevalence in the population. A measure of the contribution of a risk factor to a disease is the population attributable fraction (PAF), which is defined as the proportion by which the incidence rates of the outcome in the population would be reduced if the exposure was eliminated.¹³⁴ Wu et al.²⁶ calculated the PAF for ovarian cancer related to talc exposure in their multi-ethnic case-control study in Los Angeles. The odds ratio for genital talc use was 1.46 (95% CI 1.27 – 1.69) and the prevalence of use was 41% among the cases and 31% among the controls. The PAFs for the different ethnic groups ranged from 12.2 to 15.1%, which is interpreted as the proportion of ovarian cancer cases that theoretically could be prevented if genital talc use in the population could be eliminated and there were no changes in other risk factors. In other words, of the estimated 22,440 cases of ovarian cancer diagnosed in 2017,¹³⁵ approximately 3,300 of them could theoretically have been prevented if women had not used genital talc. The PAF calculation demonstrates that even with an

estimated relative risk for genital talc use of less than 1.5, its high prevalence of use means that it contributes to a substantial proportion of the ovarian cancer cases in the population.

The overall associations seen in the talc-ovarian cancer meta-analyses as well as in many of the individual studies are statistically significant, indicating an increase in risk of approximately 25 to 30%. While not as high as other relationships like smoking and lung cancer, these relative risks are in line with other generally accepted causal relationships (e.g., second hand smoke and lung cancer). I consider the strength of the association seen in the talc-ovarian cancer epidemiologic studies, to be an important factor in favor of a causal relationship between talc and ovarian cancer, particularly when considered along with the consistency of the association seen across these studies.

As described above, among the more than two dozen studies that have reported on the association between talc use and ovarian cancer, the vast majority of them reported relative risks or odds ratios greater than one, indicating strong consistency in the direction of the effect. The findings from the multiple studies are summarized in seven meta-analyses published since 1992, including two published in 2017-18, that combined overall results from six to 27 studies assessing genital talc exposure and ovarian cancer^{35,51,52,54,55 56 44} and in a pooled analysis published in 2013 that combined individual level data from eight case-control studies.¹⁴ Of the 27 studies included in Berge et al.'s 2017 meta-analysis⁵¹, 24 were case-control studies (18 population-based,^{13,23,25,29,30,32,33,38,39,41,42,44,45,47,50,123,136,137} 5 hospital based,^{36,43,46,49,122} and 1 with both hospital and population controls⁴⁸) and three were prospective cohort studies^{24,27,31}. The calculated overall relative risks for all studies combined in these meta-analyses were 1.3 (95% CI 1.1 – 1.6),⁴⁴ 1.27 (95% CI 1.09-1.48),⁵⁵ 1.36 (95% CI 1.24-1.49),³⁵ 1.33 (95% CI 1.16-1.45),⁵⁴ 1.35 (95% CI 1.26 - 1.46),⁵² 1.22 (95% CI 1.13-1.30)⁵¹ and 1.31 (95% CI 1.24-1.39)⁵⁶ and 1.24 (95% CI 1.15-1.33) in the pooled analysis of eight case-control studies.¹⁴ The conclusions from these analyses were quite consistent, even with additional data accumulating over time, indicating that women who used talc products as compared to women who reported no talc use were at 22 to 36% increased risk for ovarian cancer.

When considering the consistency from a number of different studies and meta-analysis, an epidemiologist should evaluate potential sources of bias including but not limited

to publication bias, recall bias, selection bias and information bias. I discuss each of these below.

Publication Bias: When considering a body of epidemiologic evidence from multiple studies, several concerns arise about the completeness of the published data and whether there is selective publishing of studies that find significant positive associations. These concerns were addressed by two distinct analyses conducted in the most recent meta-analyses by Berge, et al. (2017) and Penninkilampi and Eslick (2018).^{51,56} The first approach reported was a funnel plot, which is a graphical technique that plots the relative risks derived from the studies on one axis and the standard error of the relative risk (an indicator of the size of the study) on the other. The concept driving this approach is that studies should cluster around the “true” relative risk in the population. Due to random statistical variation, some studies will have relative risks that are higher than the true relative risk and some will be lower than the true relative risk. As sample sizes increase, there should be more precise estimates of the relative risk, therefore larger studies would be expected to produce estimates closer to the true relative risk whereas smaller studies may produce results that deviate further from the relative risk in the overall population. When the study results are plotted, one would expect them to fall into a funnel shape, with the larger studies at the point of the funnel, clustered around the true relative risk in the population, and smaller studies, with more variation in results, showing greater deviation from the average, forming the wide part of the funnel. Notably, in these meta-analyses, the two studies with the highest relative risk estimates (Chen, et al.⁴⁵ with a relative risk of 3.90 and Godard, et al.³⁸ with a relative risk of 2.49) and the two studies with the lowest relative risks (Hartge, et al.⁴⁹ and Gonzalez, et al.²⁴) all had a modest number of cases (≤ 170).

A funnel plot provides a method for assessing publication bias, i.e., the bias that results from studies with statistically significant findings being more likely to be published than studies that show no association. If one is concerned that studies that showed no association between the exposure and outcome are less likely to be published, the funnel plot allows the visual assessment of this potential bias. A lack of symmetry in the funnel plot, with a deficit of studies showing no association between the exposure and outcome, would be an indication of

publication bias. The papers by Berge, et al.⁵¹ and Penninkilampi and Eslick⁵⁶ which are the only meta-analyses that specifically addressed publication bias, concluded that there was no serious publication bias based on both visual inspection of the funnel plot and a statistical assessment of the data from the funnel plot. Therefore, there is a high level of confidence that there has not been preferential publication of studies that found a positive association between talc and ovarian cancer.

A second approach used by Berge, et al.⁵¹ was a cumulative meta-analysis, in which they showed the estimated summary relative risks over time from the first published report in 1982 through the most recently published studies in 2016. The plot showed that after the first initial reports, the overall summary estimates stabilized with estimates in the range of 1.2 to 1.25 over the last 25 years even as more and more data accrued from additional published studies.

These quantitative analyses indicate that it is unlikely that there is publication bias in the talc and ovarian cancer literature (i.e., the analyses do not suggest that studies that found talc use to be a risk factor for ovarian cancer were more likely to be published than those that found no association). Furthermore, from a qualitative perspective, it is also unlikely that there is a substantial risk for publication bias. Given the considerable public health interest in the risk for ovarian cancer associated with a widely-used cosmetic product, it is probable that any well-designed and conducted study that addressed this question would be published, even if it had null findings. Notably, one of the most recent studies, the Sister Study,²⁴ was published even though it found no increased risk for ovarian cancer associated with talc use.

While the overall conclusions from the meta-analysis and pooled analyses are quite consistent, with an overall statistically significant estimate of the relative risk in the range of approximately 1.2 to 1.3, it is important to consider possible reasons for heterogeneity of the estimates between individual studies.

Among the individual studies that have examined the association between talc use and ovarian cancer, the majority have been case-control studies, with only three prospective cohort studies addressing this research question. The meta-analysis by Berge, et al.⁵¹ noted that the summary relative risk was driven by the stronger associations observed for case-control studies

(relative risk = 1.26 (95%CI 1.17 – 1.35) than for cohort studies (relative risk = 1.02 (95% CI 0.85 – 1.20), which leads one to try to understand possible reasons for the differences by study design and to consider the relative advantages and disadvantages of the different study designs, specifically in relation to the study of talc and ovarian cancer. While the cohort studies do not show a statistically significant association for ever use of talc and ovarian cancer overall, the recent meta-analysis by Penninkilampi and Eslick⁵⁶ reported a statistically significant association with the invasive serous subtype of ovarian cancer, which is both the most common subtype and the one with the worst prognosis.

Case-Control Studies – Strengths and Weaknesses: Case-control studies, which are very commonly used in cancer epidemiology, have particular advantages for studying a relatively uncommon cancer like ovarian cancer, which has an annual incidence (number of new cases) in the United States of approximately 11 cases per 100,000 women.¹³⁸ In this study design, women with ovarian cancer (the case group) are identified by the research team, typically through a cancer registry, shortly after receiving their diagnosis. A control group of women who do not have the disease are also identified and recruited for the study. Both the cases and the controls provide information on their past exposure history. In a typical case-control study, the study participants complete an extensive questionnaire focusing on a broad range of exposures that are hypothesized to either increase or decrease the risk for cancer. In regard to ovarian cancer, a typical questionnaire will include questions on demographic characteristics, reproductive characteristics like pregnancy and contraception, medical characteristics, family history of cancer and lifestyle characteristics such as dietary factors, smoking history, physical activity and talc use. Notably, some of the factors queried about are expected to increase risk (e.g., family history of ovarian or breast cancer, estrogen use during menopause, talc), whereas others are associated with reduced risk (e.g., oral contraceptive use, pregnancies).

One major advantage of a case-control study is that it is possible to identify and recruit a large number of cases within a relatively short timeframe. To illustrate this point, I will use the example of AACES, the case-control study that my colleagues and I initiated in 2010 to study ovarian cancer in African American women and which was the source of the data we used for our 2016 paper on talc and ovarian cancer.^{1,13} We have enrolled more than 600 women with

ovarian cancer and more than 700 control women over a period of approximately 6 years, making it by far the largest study of ovarian cancer in African American women. When the grant application was originally submitted to the National Cancer Institute, one reviewer expressed the opinion that a cohort study would be preferable to the case-control design we proposed. In our response to the review, we pointed out that a prospective cohort study was not feasible for studying ovarian cancer in this population if we hoped to obtain meaningful information in a reasonable timeframe. The Black Women's Health Study, a large prospective cohort study, enrolled approximately 60,000 women starting in 1995 with the goal of studying a wide variety of health outcomes in this population. (<https://www.bu.edu/bwhs/>) In regard to ovarian cancer, after 18 years of follow-up, only 115 cases of ovarian cancer had been diagnosed among women in the cohort.¹³⁹ Although a cohort of 60,000 women is a very large epidemiologic cohort, it is still inadequate to study a relatively uncommon disease like ovarian cancer in a time-efficient manner. We successfully made the argument to the reviewers that a case-control study was the only feasible way to investigate the etiology of ovarian cancer in a timely manner in the African American population. This example illustrates why it is to be expected that the majority of the epidemiologic studies of ovarian cancer would be case-control studies.

Although case-control studies are commonly used in epidemiologic studies of cancer, there are potential biases associated with this study design, including selection bias and recall bias. In this study design, the investigator must select a control group of individuals without the disease being studied as a comparison group to determine the relative frequency of the exposures in the case group as compared to the control group. The goal of selecting a control group is to identify a group that is representative of the population from which the cases arose. This is often stated in textbooks as if someone in the control group were to develop the disease being studied, s/he would have been selected as a case for the study. There are many possible strategies for identifying and recruiting population-based controls, including the use of town registry books,^{25,50} telephone recruitment through random digit dialing^{13,25,29}, neighborhood recruitment,³⁰ driver's license records²⁵ and electoral rolls.¹²³ In hospital-based case-control studies, controls are typically selected from other hospitalized patients, with different studies

applying different criteria for eligible diagnoses among the controls, including other cancer diagnoses or specific non-cancer diagnoses.^{36,43,46,49,122}

Among the studies included in the recent meta-analyses, six were hospital-based case-control studies.^{36,43,46,48,49,122} The individuals that comprised the control group varied between these studies including patients with non-gynecologic malignancies,³⁶ patients treated for conditions other than gynecologic or malignant diseases,¹²² patients treated for conditions other than those related to reproductive history or oral contraceptive use,⁴⁶ patients treated for conditions other than gynecologic, psychiatric, or malignant diseases or pregnancy,⁴⁹ both hospital patients and population-based controls⁴⁸ and hospital visitors.⁴³ While the use of hospital controls may be efficient, concerns are often raised as to whether the controls are representative of the population from which the cases arose in terms of the exposures they experienced or their underlying risk for cancer. This is a particular concern with the study by Wong, et al,³⁶ which is the largest of the hospital-based case-control studies and one that found no association between talc use and ovarian cancer (OR=0.92, 95% CI 0.24-3.62). The control group in this study was “female patients treated for non-gynecologic malignancies during the same period”. Standard epidemiologic textbooks (e.g., Rothman, *Modern Epidemiology*¹⁴⁰) state that controls should be selected from the same source population or study base that gives rise to the cases. It is difficult to make the argument that other cancer patients represent the source population from which the ovarian cancer cases arose, which suggests that this was a poor choice of a control group that could have led to biased findings.

Another of the hospital-based studies, the study by Tzonou et al.⁴³ which reported a relative risk of 1.05, also had a significant limitation. This study was conducted in Greece, and the overall prevalence of talc use in the study population was 3.5%. Given the small sample size and the low prevalence of exposure, this population was ill-suited to study the relation between talc use and ovarian cancer.

As noted in the meta-analysis by Penninkilampi and Eslick,⁵⁶ the hospital-based studies were older (published before 2000) and with the exception of the Wong study³⁶, all were smaller studies that included fewer than 200 cases. The summary odds ratios from the hospital-based studies was lower but not significantly different than the summary odds ratio from

population-based studies (OR 1.22 versus 1.33, respectively),⁵⁶ a result that is not surprising given the important limitations in some of the hospital-based studies.

While there is no ideal method for control selection, arguably population-based control recruitment is more likely to result in a control group that is representative of the population from which cases arose. All of the larger case-control studies that investigated talc use and ovarian cancer (i.e., those with more than 500 cases) were population-based,^{13,23,25,29,30,33,42,123,137} which should have minimized selection bias.

Recall Bias: Recall bias is another possible bias in case-control studies. Recall bias is defined as systematic error due to differences in accuracy or completeness of recall of prior events or experiences.¹³⁴ It is a concern with case-control studies because information on exposures is obtained through interviews or questionnaires completed after the cases have already been diagnosed with the disease. It is thought that people affected with a disease may have given more thought to possible causes of that disease and have more accurate recall of risk factors than a person serving as a control in the study.

A distinction is made between *recall bias*, which arises from cases recalling exposures differently than controls, and *inaccurate recall* of an exposure that is difficult to remember with precision. Recall bias, which is considered differential misclassification between cases and controls, can result in either an overestimate or underestimate of the true relative risk. Inaccurate recall that occurs to a similar degree in cases and controls is considered non-differential misclassification, and for a dichotomous outcome (e.g., ever vs. never use of talc) will typically result in an underestimate of the true relative risk. An exposure like talc use, especially when assessing use over many years, is clearly one that is subject to a certain amount of inaccurate recall. However, inaccurate recall alone would not result in the consistently increased relative risks observed in the vast majority of the case-control studies of talc use and ovarian cancer.

Therefore, recall bias, which theoretically could result in a biased estimate of the relative risk, must be considered. Situations where recall bias would be considered a particular threat to a study's validity would be: 1) the exposure of interest is one that could be considered sensitive (e.g., illicit drug use, induced abortions), 2) the study hypotheses are known to the

study subjects or interviewers, or 3) there has been considerable media attention focused on an exposure.

In regard to the first situation, genital talc use, while addressing a rather personal topic, would not be considered a particularly sensitive topic. One would not expect that women would be disinclined to report its use out of embarrassment or a desire to report what is perceived to be more socially acceptable as has been reported for exposures like induced abortion.¹⁴¹

As to the second point regarding the blinding of the interviewers and the study participants to the study hypotheses, this is standard practice in epidemiologic research. In addition, in the typical case-control study, the investigators are collecting a tremendous amount of questionnaire data to address numerous hypotheses and there is not a particular focus on a single exposure. As an example, the questionnaires from AACES and the North Carolina Ovarian Cancer study each took approximately 1 - 1.5 hours to administer and collected information on a large number of exposures including pregnancy history, contraceptive and hormone use, family history of cancer, medical history, psychosocial factors and lifestyle factors. Data were collected on factors that were expected to be associated with increased risk (e.g., family history of cancer, history of infertility, menopausal hormone use, talc use) as well as those expected to be associated with decreased risk (e.g., oral contraceptive use, pregnancies, physical activity). Given the broad range of hypotheses and the numerous exposures that the cases and controls were queried about and the fact that neither cases nor controls were told in advance of the interview about the specific topics that would be covered, it is unlikely that the women with ovarian cancer would have given more thought to their talc use resulting in substantial systematic over-reporting of talc use among cases. This is supported by studies of other cancers that used empirical data to assess the likely effect of recall bias on relative risk estimates when investigators examined numerous exposures and concluded that recall bias did not consistently lead to increased estimates of the relative risk.¹⁴²⁻¹⁴⁴

Further evidence that recall bias in case-control studies does not inevitably lead to an overestimate of the association between a risk factor and exposure comes from a recent review of meta-analyses of observational studies by Lanza et al.¹⁴⁵ This review analyzed a random

sample of 23 meta-analyses of observational studies addressing different exposure/disease associations published in 2013 and compared findings from case-control studies and cohort studies within individual meta-analyses to determine if conclusions from case-control studies were significantly different from those from cohort studies. The authors concluded that there was no significant difference in effect estimates between the case-control and cohort studies, suggesting that the study design did not have an important impact on the conclusions of the meta-analyses. Although recall bias *theoretically* could lead to an overestimate of the association between a risk factor and disease, the empirical evidence indicates that in practice the effect is small in most situations.

The third situation of the effect of media attention on an exposure deserves consideration as there has been reporting in the lay press in recent years about lawsuits involving talc and ovarian cancer. This concern is not relevant to the vast majority of the studies as virtually all of the data collection in the epidemiologic studies of talc and ovarian cancer occurred prior to such litigation. However one notable exception is AACES,¹³ which began enrollment in 2010 and included data collected up through August, 2015. At the recommendation of the reviewer who critiqued the manuscript when it was submitted for publication, our group examined the association between talc and ovarian cancer stratified by the date of enrollment. The odds ratio for genital talc use and ovarian cancer was 1.44 for the overall study population and 1.19 for the participants interviewed before 2014. These data do give some credence to the idea that recall bias could have led to the higher odds ratios when including women interviewed during the time when there was more media attention focused on this exposure, however the fact that the association was attenuated but not eliminated when considering the full study population suggests that the association is not due entirely to recall bias.

Another way to approach the issue of whether recall bias is a likely explanation for the association between talc use and ovarian cancer is to consider whether the association was observed for other gynecologic cancers. The data are admittedly very sparse in this regard, however the only published case-control study of talc use and endometrial cancer reported an odds ratio of 0.88 (95% CI 0.68 – 1.14).⁶⁷ A study of ovarian cancer that was conducted by

several of the same investigators as the endometrial cancer study used similar methodology, was conducted in a similar timeframe (early to mid-2000s) in the same geographic region (Australia) and reported a similar prevalence of talc use in the study population. In contrast to their endometrial cancer study in which the investigators observed a non-significant inverse association with talc use, the investigators found a statistically significant increased risk for ovarian cancer associated with talc use (odds ratio=1.17, 95% CI 1.01 – 1.36).¹²³ While this comparison clearly needs to be interpreted cautiously because there is only a single published case-control study of talc use and endometrial cancer, it does provide evidence to suggest that the association between talc and ovarian cancer observed in most case-control studies is not due simply to recall bias.

Cohort Studies – Strengths and Weaknesses: In contrast to the case-control study, the prospective cohort study design is less susceptible to the selection bias and recall bias described above. Women who develop cancer and the comparison group are from the same population (the cohort) so the bias that could arise from improperly selecting a control group is minimized. Similarly, because the exposure information is collected before the diagnosis of cancer, one would not expect that recall of exposures would differ between the women who went on to develop cancer and those who remained free of cancer.

Despite these advantages, cohort studies do have some important disadvantages in relation to studying cancer etiology. The first is that even with large cohorts, it takes many years for a reasonable number of cancers to develop within the cohort, especially for an uncommon cancer like ovarian cancer. When considering the statistical power of a study to assess the association between an exposure and a disease, the size of the cohort is not the only driver of study power. A more critical consideration is the number of cases that develop within the cohort, which in turn is dependent on the length of follow-up of the larger cohort. Therefore, a large cohort with a relatively short duration of follow-up during which time a small number of cases developed among cohort will have low statistical power. In contrast, the total sample size of a case-control study is likely to be much smaller than a cohort study, but if it has a larger number of cases, it will have greater statistical power than the cohort study.

Among the three cohort studies included in the most recent meta-analysis,⁵⁶ the Nurses' Health Study reported 307 cases in a cohort of 78,630 women after approximately 14 years of follow-up,^{34,146} the Women's Health Initiative reported 429 cases in a cohort of 61,576 women after a mean of 12.4 years of follow-up²⁷ and the Sister Study reported 154 cases in a cohort of 41,654 women after a mean of 6.6 years of follow-up.²⁴ Even with tens of thousands of women in these studies, the number of ovarian cancer cases within each cohort is smaller than the number of ovarian cancer cases in many of the case-control studies. In particular, the number of cases within the Sister Study is smaller than the number of cases in any of the case-control studies published since 1993. As described in a commentary by Narod⁸¹, the lack of a significant overall association between ever use of talc and ovarian cancer in the cohort studies may be due to the fact that despite the large size of the cohorts, the studies were not adequately powered to detect a relative risk of approximately 1.2.

Another limitation of cohort studies that is of greater relevance to the question of talc use and ovarian cancer is information bias related to exposure assessment. Cohort studies are typically designed to examine many different outcomes that develop within the study population over time. The Nurses' Health Study (<http://www.nurseshealthstudy.org/selected-publications>) and Women's Health Initiative (<https://www.nhlbi.nih.gov/whi/references.htm>) have reported on many different outcomes including, but not limited to, multiple types of cancer, cardiovascular diseases, fractures, gastrointestinal conditions and mental health. In contrast, case-control studies focus on a single disease, such as ovarian cancer. Because cohort studies are designed to examine diverse outcomes, the questionnaires must obtain data on risk factors that are relevant to a wider variety of diseases. To keep the questionnaire to a manageable length, a cohort study will typically query about more risk factors but in less detail than a case-control study that is focused on a single disease. This is the case with the talc questions, with the cohort studies collecting less detailed information on talc use, especially in regard to duration and frequency of use, than most of the case-control studies.

It is also worth noting that cohort studies are also subject to recall errors, especially when assessing exposures that began early in life. When the cohort studies assessed talc use, they were asking women to recall their past use of the products up to the point of interview,

similar to how exposure is assessed in the case-control studies. In the Nurses' Health Study, the cohort members were aged 36 to 61 at the time talc use was assessed in 1982, and in the Women's Health Initiative, the mean age at enrollment was 63. Because many women initiate use of talc at a young age, the study participants would have been recalling exposures over several decades, and it stands to reason that there would be some errors in recall. Therefore, in cohort studies as in case-control studies, reported talc use was subject to some degree of inaccurate recall. This likely resulted in non-differential misclassification of the exposure, which usually results in an underestimate of the true relative risk.

Another concern with exposure assessment in cohort studies that is highly relevant to the question of talc use in relation to ovarian cancer is that risk factor information can change over time. If the questionnaire data that were collected when the cohort was assembled do not include a comprehensive exposure history to that time point and are not updated over time, the information may not reflect the complete exposure history of an individual in the time before she was diagnosed with cancer. This could result in some talc users being incorrectly identified as non-users or in incorrect estimates of the duration of exposure.

Incomplete exposure assessment is a potential problem for each of the three cohort studies that have reported on talc use and ovarian cancer, however it is a particular issue for the Sister Study²⁴ which reported a non-significant inverse association between talc use and ovarian cancer (relative risk of 0.73, 95% CI 0.44 – 1.20). Each of the cohort studies assessed talc use at a single point in time and did not update the information at subsequent follow-up interviews. The Nurses' Health Study collected limited information on talc exposure in 1982, and did not collect additional data on talc use in subsequent questionnaires between 1982 and when the results were described in papers published in 2000³⁴ and 2010.¹⁴⁶ Similarly, the Women's Health Initiative collected information on talc exposure when the women were enrolled into the study and did not obtain updated information during the years the cohort was followed. Therefore, any use of talc after that single exposure assessment was not captured, and there would be a certain amount of misclassification of the exposure in both the women who subsequently developed ovarian cancer and those who did not. If the misclassification was non-differential, meaning that the degree of misclassification was similar between the women

who developed ovarian cancer and those who did not, the predicted effect would be a bias towards the null.¹⁴⁰ In other words, non-differential misclassification of talc exposure (as a dichotomous variable) would mean that the observed relative risk was not as strong as it would have been if there had been not misclassification.

The degree of misclassification of exposure in the Sister Study²⁴ is apparently much greater than in the other cohort studies. Use of talc was assessed through questions about personal care products used only in the 12 months prior to enrollment, including genital talc use in the form of powder or spray applied to a sanitary napkin, underwear, diaphragm, cervical cap or vaginal area. This assessment is essentially a “snapshot” of talc use during a short period of time, capturing neither the cumulative use of talc up to that point nor any subsequent use of talc after the baseline interview. Not surprisingly, the reported prevalence of talc use was quite low in this study. The 14% prevalence reported in the Sister Study was markedly lower than the other two cohort studies (40.2% in the Nurses’ Health Study³⁴ and 52.6% in the Women’s Health Initiative²⁷) as well as in nearly all of the case-control studies. In addition to underestimating the prevalence of talc use in their population, their assessment of talc only during the year prior to enrollment probably did not capture exposure during the most relevant period of the woman’s life. As the authors acknowledged in their paper, if latency (the time between exposure and diagnosis of cancer) is 15 to 20 years, the exposure assessments do not accurately reflect the period of risk. The limitations in the assessment of talc use raise serious questions about the validity of the findings from the Sister Study for this particular exposure. It is impossible to predict the direction or the magnitude of the association between talc use and ovarian cancer if the Sister Study had conducted a more complete assessment of the exposure.

A further limitation of the exposure assessment in the Nurses’ Health Study and Women’s Health Initiative is that neither assessed both the frequency and duration of use of talc. This additional limitation has ramifications for assessing dose-response gradients, which will be discussed in a later section of this report.

While cohort studies are often considered a stronger study design for assessing causal relationships between an exposure and outcome, this is not absolutely true for all exposures and outcomes. Rather than making a judgement about the quality of evidence based solely on

study design, it is important to consider study design from a more nuanced perspective and consider whether a cohort or case-control study provides the most optimal assessment of the exposure and outcome. As described above, each of the three cohort studies that has addressed talc use and ovarian cancer risk had substantial limitations in their assessment of talc use within their study population, which weakens their conclusions that talc use is not significantly associated with ovarian cancer risk.

In addition, the Sister Study,²⁴ which is a study that was designed primarily to examine breast cancer outcomes among women who had a sister with breast cancer, the small number of ovarian cancer cases despite the large size of the cohort and the inadequate assessment of talc exposure arguably make it a much weaker study than some of the larger, well-designed population-based, case-control studies. Notably, this study, with a relative risk estimate of 0.73 (95% CI 0.44 – 1.20)²⁴ could be considered an outlier as it is only one of two studies that reported a relative risk substantially less than 1, the other being Hartge's 1983 hospital-based case-control study.⁴⁹

Uncontrolled Confounding in Observational Studies: Uncontrolled confounding is a potential concern in both case-control and cohort studies since they are observational studies. If a factor is associated with talc use *and* is a risk factor for ovarian cancer and is not accounted for in the statistical analysis, it could confound the association between talc use and ovarian cancer. In other words, if there is confounding, the increased risk observed with talc use could be due to the failure to account for the other risk factor. Vaginal douching, which was found to be associated with ovarian cancer risk in the Sister Study, was examined as a potential confounder of the association between talc use and ovarian cancer.²⁴ Their analyses showed that adjusting for douching using statistical modelling had a negligible effect on the association between talc use and ovarian cancer, providing no evidence of confounding. Other studies have either found an association between talc and ovarian cancer when controlling for douching⁴⁴ or found no association between douching and ovarian cancer,⁴⁹ thus the available data do not support that douching is a confounder of the association between talc and ovarian cancer. Although uncontrolled confounding is a theoretical possibility, to my knowledge, in the more

than 30 years of research on talc and ovarian cancer no such confounder has been identified that could account for the increased risk associated with talc use.

Overall, the meta-analyses indicate a high level of consistency in findings, especially from the case-control studies. Although weaker associations were observed in the cohort studies, the most recent meta-analysis did report statistically significant associations with invasive serous ovarian cancer in the cohort studies as well as in the case-control studies that reported on histologic subtype.⁵⁶ As a whole, the weaker associations observed for the cohort studies could be plausibly explained by limited methods used for talc exposure assessment, the limitations described above, including the most recent cohort study by Gonzalez, et al.,²⁴ which will have the predicted effect of biasing the results towards the null (i.e., showing an effect that is weaker than the true effect).

Taken as a whole, the overwhelming statistical strength of these studies, whose results are replicated over decades across a wide variety of populations and investigators, further supported by consistent meta-analysis, weighs very heavily in favor of a causal inference.

Temporality

Temporality is the only consideration that is an absolute criterion when making a judgment of causality. This criterion states that a cause (the exposure) must precede the effect (the outcome of interest) in time. Both the cohort and case-control studies that examined talc use in relation to ovarian cancer assessed talc exposure that preceded the diagnosis. In cohort studies, the questionnaire data are obtained before any women in the cohort have a diagnosis of ovarian cancer, and in the case-control studies, women with ovarian cancer are asked to report on exposures that occurred before their diagnosis and controls are asked to report on exposures that occurred in a similar time frame. Therefore, there is no question that the exposure assessment captured talc exposure that preceded the diagnosis of ovarian cancer. Nevertheless, this factor is not highly weighted; while its absence would be fatal to a causal inference, its presence is not particularly compelling support for causation.

Biological Gradient

Associations that show evidence of a biological gradient, or dose-response relationship, are considered to have stronger evidence of causality. While the inconsistencies in reported dose-response trends for talc and ovarian cancer have been noted in some meta-analyses and reviews, e.g.,^{51,54} there are several considerations about this exposure that should be taken into account.

First, for an association like talc and ovarian cancer, the dose that is most relevant is the amount of talc that actually reaches the fallopian tubes and ovaries. The epidemiologic data rely on measures of external application as a surrogate of the level of exposure, not the actual exposure in the upper genital tract.

Second, there is some inherent inaccuracy in the measurement of the exposure, as the participants in most studies were asked to recall their duration and/or frequency of use over many years.

Third, the dose of talc exposure has been assessed differently across the studies. Some studies assessed only duration of use (months or years), some assessed only frequency of use (e.g., number of days per month) and some used measures of both duration and frequency to come up with a measure of total dose (estimated lifetime number of applications). The limitations of relying on duration or frequency alone as a measure of talc dose are apparent. For certain exposures, oral contraceptive use for example, duration of use is a good measure of total exposure because the pills are taken once daily. In contrast, patterns of talc exposure may be more inconsistent. Some women may use it daily, others only during their menstrual periods, others may apply it only during certain times of the year and others may have still different patterns of use. Measures of exposure based only on duration of use or only on frequency of use could result in inaccurate estimates of total exposure and obscure a dose-response relationship.

Some of the meta-analyses have cited the lack of a clear dose-response relationship as an argument against talc being a cause of ovarian cancer, and when considering measures of either years of talc use or number of applications of talc per month, there is considerable heterogeneity across studies. When considering the studies that examined dose-response associations considering both dose and frequency to estimate the total number of applications

of talc,^{13,14,25,29,30,32,35,41}, the majority^{13,14,25,30,32} did find significant trends of higher risk with more lifetime applications of talc.

Terry, et al.¹⁴ noted in the pooled analysis of eight case-control studies that the trend for increasing risk for non-mucinous ovarian cancers with an increasing number of genital powder applications was significant when non-users were included in the analysis, but the trend was not significant when the analysis was restricted to ever users. The authors therefore concluded that the significant trend was largely due to the comparison of women who had ever used talc versus those who had never used it, suggesting that the dose-response relationship was not a simple linear increase in risk with greater exposure to talc.

While there is evidence of a dose response relationship in the majority of the studies that considered both frequency and duration of use (i.e., total number of applications), these observations are less consistent than the overall association between talc and ovarian cancer. There are several possible reasons why not all studies observed dose-response relationships, even when an overall association was observed in the study. First, there is likely to be greater inaccuracy in the recall of duration of use as compared to ever/never use, which would tend to obscure a dose-response relationship. Second, when “ever-users” were stratified into duration of use categories, it often resulted in strata with small numbers of women, resulting in less stable relative risk estimates within the duration categories. Third, as noted by Terry, et al.¹⁴, the dose-response relationship may not be a simple linear trend. In many of the studies, even the women in the lowest exposed category had hundreds of episode of talc exposure. Because there could have been considerable exposure even among the women in the “low” exposure categories, greater exposure may not have resulted in substantially increased risk and thus a linear trend may not have been apparent.

Overall, biological gradient was given lesser weight in my assessment of the literature, based on: 1) some of the studies that assessed a dose-response relationship evaluated only duration or frequency of use and not total number of applications, 2) duration and frequency of use are subject to more misclassification than ever use of talc, 3) small sample sizes within strata lead to unstable estimates, and 4) there is the possibility of a non-linear dose-response relationship. Nonetheless, even with these limitations, there was still evidence of a dose-

response relationship in the majority of studies that evaluated it based on the total number of applications.

Biologic Plausibility

Biological plausibility refers to whether there is a reasonable biological mechanism through which the exposure could lead to the disease. Hill is quick to point out that biological plausibility depends on the current state of scientific knowledge. Specifically, Hill wrote “It will be helpful if the causation we suspect is biologically plausible. But this is a feature I am convinced we cannot demand. What is biologically plausible depends upon the biological knowledge of the day.” It is clear that from these statements that the consideration of biological plausibility does not require that there is a *proven* biological mechanism to make a judgment of causality between an exposure and disease. Therefore, for this Hill consideration, a scientist looks for biological evidence that might explain the associations that are observed in the epidemiologic studies. In other words, one has to see whether the observed association “makes sense” biologically. In this case, I have considered both clinical plausibility and biological plausibility. Both of these show that the association seen in the epidemiologic studies “makes sense.”

It is probably safe to say that our understanding of the complex biological processes that lead from exposure to disease is incomplete for all cancers. In some instances, the precise biological mechanisms by which an exposure leads to disease remain unclear and in others, some mechanisms are well-established but there is not a complete understanding of why some exposed individuals develop the disease and others do not. An example of the former is alcohol consumption as a cause of breast cancer. While alcohol is considered by IARC to be an established cause of breast cancer,¹²⁸ recent publications still describe the association as one in which the exact biological pathways are unclear, even though several possible mechanisms have been hypothesized (i.e., metabolism to acetaldehyde or effects on estrogen levels).^{147,148} An example of the latter is smoking and lung cancer. Mechanisms of carcinogenesis from constituents of tobacco smoke have been well-described,¹⁴⁹ however it remains unclear as to why some smokers are more susceptible to developing lung cancer. In short, it is important to

recognize that biological plausibility depends on the current state of knowledge and may evolve over time as new evidence emerges.

When considering the likelihood of talcum powder products causing ovarian cancer, there is robust data that leads to the conclusion that there are biologically plausible mechanisms by which this exposure could lead to ovarian cancer. Specifically, 1) talcum powder products can migrate from the perineum through the genital tract to the ovaries and fallopian tubes, 2) talcum powder products can become imbedded in the ovarian tissue; 3) talcum powder products can induce an inflammatory response, and 4) the inflammatory response can result in increased oxidative stress and expression of cytokines, mutagenesis, and cell proliferation.

Pathology studies have demonstrated that particles may ascend the female genital tract from the vagina to the fallopian tubes and ovaries,^{150,151} and talc particles have been identified in ovarian tissue.^{71,76,78,79} In fact, the FDA's 2014 response to the Citizen's Petition requesting a cancer warning label on cosmetic talc products states that "the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable".¹⁵² Therefore, it is highly plausible that application of talcum powder products to the genital area can result in exposure to the ovaries.

It is also plausible that inhalation of talc products could also be a route of exposure leading to cancer. Studies of asbestos exposure indicate that inhalation of asbestos fibers can result in exposures to the peritoneal tissue, through transport through the lymphatic system and/or blood.¹⁵³⁻¹⁵⁵ There is strong evidence that such exposure can result in cancer, most notably mesothelioma. Inhalation of talcum powder products could result in similar peritoneal exposure.

Given the evidence that external application of talcum powder products can reach the ovaries either through upward migration through the genital tract or through inhalation and subsequent transport through the lymphatic system and/or blood, there are plausible biological pathways by which talc could lead to the development of ovarian cancer.

It is well-established through several lines of evidence that talc can cause inflammation. The inflammatory properties of talc are exploited for clinical use in talc pleurodesis, a treatment

for malignant pleural effusions or pneumothorax that involves instillation of talc into the pleural space.^(<https://www.uptodate.com/contents/talc-pleurodesis>) The resultant inflammation and fibrosis result in adhesion of the layers of the pleura, closing the pleural space. The inflammatory properties of talc are also evident in that chronic or acute exposure to talc through inhalation which can result in pulmonary talcosis, a chronic inflammation of the lower respiratory tract.^{156,157} Animal studies also confirm that talc causes inflammation, as experiments in rats treated with intra-vaginal or perineal talc showed inflammatory changes in the genital tract.⁷⁰ Although neoplastic changes were not observed in this experiment, this could be explained by the small number of animals (n=7) in each group or the duration of the experiment (3 months).

Inflammation has been identified as one of the hallmarks of cancer, with both extrinsic and intrinsic pathways described.^{158,159} Talc would be characterized as being involved in an extrinsic pathway, in which an exposure or condition results in chronic, non-resolving inflammatory responses. Chronic inflammation can lead to a cascade of cellular events that could result in damage to DNA, increased cell division and generation of inflammatory mediators.

Recent work by Saed, Fletcher, et al.^{160,161} describes the role of oxidative stress in the pathogenesis of ovarian cancer and the effects of talc on the oxidative state of ovarian cancer cell lines. Oxidative stress results when the balance between oxidant and anti-oxidant enzymes and molecules in cells is altered, resulting in an excess of reactive oxygen species or reactive nitrogen species. Oxidative stress, which can result from numerous factors including exposure to carcinogens, infection and chronic inflammation, has been shown to affect the initiation, promotion and progression of several types of cancer. Saed, et al. have reported that talc can generate a pro-oxidant state in both normal ovarian epithelial cells and ovarian cancer cells. Exposure to talc resulted in an increase in mRNA levels of certain pro-oxidant enzymes and a decrease in the mRNA of several anti-oxidant enzymes, suggesting a possible cellular mechanism by which exposure to talc could contribute to the development of ovarian cancer.

There is also evidence in the medical literature that talc products contain additional constituents that are known ovarian carcinogens, particularly asbestos.¹⁶²⁻¹⁶⁶

Asbestos is one of the most established carcinogens in our environment, and is associated with a variety of cancers including mesothelioma, lung, larynx and ovarian.^{167,168} IARC has stated that “a causal association between exposure to asbestos and cancer of the ovary was clearly established,” based on strongly positive cohort mortality studies of women with occupational exposure to asbestos as well as studies of women with environmental exposure to asbestos.¹⁶⁹ The Occupational Safety and Health Administration has stated that “there is no safe level of asbestos exposure for any type of asbestos fiber” and that asbestos exposures as short as a few days have resulted in cancer (mesothelioma), indicating that even low levels of exposure may be carcinogenic. (<https://www.osha.gov/SLTC/asbestos/>)

Although it has been often stated that talc products manufactured after 1976 are asbestos-free, evidence from published scientific reports,^{57,162} analyses performed on samples manufactured and packaged at different time points after 1976,¹⁷⁰⁻¹⁷³ and internal documents and testimony from the defendants demonstrate that statement is inaccurate.^{174,175} There is evidence that products manufactured after 1976 are not asbestos-free. Studies from Longo, et al. show that talc products can contain asbestos and talc containing asbestiform fibers (e.g., talc occurring in a fibrous habit).^{170,171} Therefore it is reasonable to conclude that women who regularly used talc products, both before and after 1976, were likely exposed to asbestos and talc containing asbestiform fibers through their use of these products.

Analyses of talcum powder products also demonstrate the presence of other constituents such as chromium and nickel which are well established carcinogens, and cobalt which is considered a possible carcinogen.^{169,174} I have also reviewed a report analyzing the 150+ known fragrance ingredients in talcum powder products, many of which have been determined harmful to humans.¹⁷⁶ The presence of these substances provide further evidence that exposure to talc products could result in cancer

It is also plausible that even among women recently diagnosed with ovarian cancer, exposure to the pre-1976 talc products, which are generally understood to have contained asbestos and talc containing asbestiform fibers, increased their risk for ovarian cancer. It is well-established that many cancer risk factors have a long latency, which the National Cancer Institute defines as “the time that passes between being exposed to something that can cause

disease and having symptoms”. Numerous examples of cancer risk factors with prolonged latency periods exist. For example, lung cancer typically is not diagnosed among cigarette smokers for several decades after initial exposure¹⁷⁷ and having severe sunburns during childhood is a risk factor for melanoma,¹⁷⁸ which has a median age of diagnosis of 63 years.¹³⁵

It has also been reported that the latency period between exposure to asbestos and mesothelioma (the cancer most strongly linked to asbestos exposure), ranges from 15 to more than 70 years.^{179,180} The median latency has been estimated at 22 to 32 years, with longer latency periods estimated for women than for men.^{179,180} Thus, it is not unreasonable to conclude that exposure to talc products early in a woman’s life could result in ovarian cancer decades later.

Further, other established risk factors for ovarian cancer also demonstrate long latency periods. Oral contraceptive use and history of pregnancy are two of the factors that are most consistently reported in association with ovarian cancer (both of which reduce risk). Although, these are “exposures” that typically occur when women are in their teens, twenties or thirties, the median age of diagnosis of ovarian cancer is 61 years, suggesting that events and exposures from early in a woman’s reproductive life can influence her risk for ovarian cancer decades later.

The totality of this evidence indicates that there are plausible biological pathways by which use of talc products could lead to ovarian cancer. There is clear evidence that external applications of these products can result in exposure to the ovaries, through upward migration through the genital tract or inhalation exposure. Once exposed, there are plausible biological mechanisms, by which talc itself or constituents of the talcum powder product could lead to carcinogenic transformation of ovarian cells. This includes credible evidence that talc products contain asbestos fibers, a known ovarian carcinogen, regardless of whether they were manufactured before or after 1976. While it is likely that advances in scientific knowledge may further refine our understanding of how talc exposure can lead to ovarian cancer, our current knowledge is adequate to conclude that there are plausible biological pathways leading from talc exposure to ovarian cancer.

I have considered the biologic plausibility that would support and detract from the hypothesis that talcum powder products can cause ovarian cancer. The more persuasive evidence is that talc can migrate to the ovaries through the genital tract and become imbedded in ovarian tissue. It is also plausible that talc could reach the peritoneal cavity through an inhalation route. Regardless of the route of exposure, it is clear that talcum powder products, including constituents like asbestos and fibrous talc, may cause an inflammatory response and oxidative stress that could lead to cell damage. These biologically plausible mechanisms are a persuasive explanation for the consistent increased risk we have observed in the epidemiologic studies. *Simply put, the observed association “makes sense” biologically.* Along with consistency and strength, I considered this a strong factor favoring a causal inference.

Specificity

As described by Hill,¹²¹ if specificity exists between an exposure characteristic and disease, it provides strong evidence of causality. However, he also stated that “one-to-one relationships are not frequent ...multi-causation of disease is generally more likely than single causation”. Clearly, ovarian cancer has multiple causes, with talc exposure among many known risk factors. From the standpoint of there being a “one-to-one relationship” between talc and ovarian cancer, there is not a high level of specificity. However, given that talcum powder products are particularly associated with epithelial ovarian cancer, especially serous ovarian cancer, it does support that it is a fairly specific relationship. This aspect was given only modest weight, because talc is one of many possible causes of ovarian cancer.

Coherence

It is recognized that the plausibility depends on the current state of biological knowledge. Knowledge of the biological mechanisms for ovarian carcinogenesis (and virtually any other disease) is incomplete and will continue to evolve as further research continues. Coherence, as described by Hill, means that, even if the knowledge of biology of the disease is not well-defined, the “data should not seriously conflict with the generally known facts of the natural history and biology of the disease”.¹²¹ Given the current state of knowledge of ovarian

carcinogenesis, the postulated mechanisms by which talc exposure leads to ovarian cancer do not conflict with the current state of knowledge on ovarian carcinogenesis. This aspect was given considerable weight as it is important that the overall evidence fit together in a coherent manner. Taking into account the plausible pathways by which talc products could reach the target tissue, the expected latency period between exposure and disease, and biological mechanisms that are consistent with our knowledge of carcinogenesis, the data are consistent with the natural history and biology of ovarian cancer.

Experiment

As described above, the epidemiologic data on talc use and ovarian cancer are from observational studies, therefore there are no clear cut experimental data on which a causal assessment can be made. Hill acknowledged that experimental data are often not available for the exposure/disease associations under study, but in some circumstances, experimental or semi-experimental evidence is available.¹²¹ For example, if a preventive action is taken to remove the exposure and the incidence of disease declines, there is strong support for a causal relationship. No such experimental evidence is available for talc use and ovarian cancer.

Analogy

The final viewpoint defined by Hill ¹²¹ is analogy, whereby evidence of an association with one risk factor would suggest that a similar risk factor could also plausibly be associated with the disease. Because this viewpoint is rather vague, it is often not incorporated into causal assessments. Nevertheless, while I did not weight it heavily, the similarity between asbestos and asbestiform talc – both of which are widely accepted as causing ovarian cancer – is supportive of this viewpoint.

Conclusion

Epidemiologic evidence linking genital talc use to ovarian cancer has been accruing since 1982.⁵⁰ As I evaluated this evidence, I considered the results from individual studies with different designs (case-control and cohort) as well as meta-analyses and a pooled analysis of

multiple case-control studies. In my evaluation of the data, I considered the strengths and weaknesses of individual studies, recognizing that there are advantages and disadvantages of both case-control and cohort studies for evaluating talc as a risk factor for ovarian cancer. I used the Bradford Hill framework as a guide for making my weight of the evidence assessment of whether there is evidence for a causal association between talc use and ovarian cancer.

The epidemiologic evidence I evaluated was derived from more than two dozen studies conducted in many different settings. The vast majority of studies reported relative risks or odds ratios greater than one, indicating that women with ovarian cancer were more likely to have used talc products than women without ovarian cancer. Meta-analyses, which combine findings across multiple studies to come up with an overall estimate of risk that is more statistically robust, have consistently reported that there is a statistically significant increased risk for ovarian cancer among women who reported genital talc use. While meta-analyses have noted that the relative risk estimates from case-control studies have been larger than from cohort studies, limitations in all of the cohort studies could explain the weaker associations observed in these studies. It is also noteworthy that the most recent meta-analysis⁵⁶ reported significantly increased risks for invasive serous ovarian cancer, which is the most common subtype as well as the one with the worst prognosis, in both cohort and case-control studies.

The epidemiologic studies that have examined talc use in relation to ovarian cancer risk have been conducted in very diverse populations, both within and outside the United States and in women of different race/ethnicities. The consistency of the findings across populations adds credibility to the findings of increased risk of ovarian cancer among talc users.

The relative risk estimates in most studies and the summary relative risk estimates from the meta-analyses are of a magnitude (~1.25-1.30) that is comparable to other common exposures that are causally related to cancer (e.g., passive smoke exposure and lung cancer, oral contraceptive use and breast cancer, menopausal estrogen use and breast cancer, residential radon exposure and lung cancer). Additional evidence supportive of talc being an ovarian cancer risk factor are biologically plausible mechanisms based on inflammation pathways, oxidative stress and the presence of asbestos, asbestiform talc, and other known

carcinogens in talcum powder products. Evidence of a dose-response relationship exists in many of the studies that considered both duration and frequency of exposure.

Based on the evidence in total, it is my opinion with a reasonable degree of scientific certainty that use of talcum powder products can cause ovarian cancer. I reserve the right to modify or refine my opinions based on additional scientific evidence that may emerge on this topic.

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EXHIBIT A

***Duke University Medical Center
Curriculum Vitae***

Date Prepared: October 2018

Patricia Gripka Moorman, M.S.P.H., Ph.D.

Primary academic department: Department of Community and Family Medicine
Duke University Medical Center

Present academic rank and title: Professor with tenure, September 2014

**Date and rank of first Duke
faculty appointment:** July 1, 2000, Assistant Professor

Medical licensure: N/A

Date of birth: December 19, 1957

Place of birth: Kansas City, Kansas, USA

Citizen of: United States of America

EDUCATION

	Institution	Year	Degree
High School	Bishop Ward High School Kansas City, KS	1975	Diploma
College	University of Kansas Lawrence, KS	1980	B.S. with distinction, Pharmacy
Graduate School	University of North Carolina – Chapel Hill Chapel Hill, NC	1989	M.S.P.H., Epidemiology
	University of North Carolina – Chapel Hill Chapel Hill, NC	1993	Ph.D., Epidemiology

PROFESSIONAL TRAINING AND ACADEMIC CAREER

Institution	Position/Title	Dates
Shalinsky Drugs, Kansas City, KS	Pharmacist	1980-1981
Community Pharmacy, Wrentham, MA	Pharmacist, Manager	1981-1982
Revco Drugs, Durham/Raleigh, NC	Pharmacist, Manager	1983-1993
Department of Epidemiology University of North Carolina - Chapel Hill	Graduate Research Assistant Teaching Assistant	1987-1993
Burroughs Wellcome Research Triangle Park, NC	Epidemiology Research Associate Summer Intern	1988
Department of Epidemiology Lineberger Comprehensive Cancer Center University of North Carolina - Chapel Hill	Research Assistant Professor	1994-1996
Dept. of Epidemiology and Public Health Yale Comprehensive Cancer Center Yale University School of Medicine New Haven, CT	Associate Research Scientist	1997-2000
Department of Epidemiology University of North Carolina - Chapel Hill	Adjunct Assistant Professor Adjunct Associate Professor	2000-2005 2005-present
Dept. of Community and Family Medicine Duke University Medical Center	Assistant Professor Associate Professor (non-tenured) Associate Professor (tenured) Professor (tenured) Clinical Research Unit Director (formerly Site-Based Research Director)	2000-2004 2004-2008 2008-2014 2014-present 2009-present

PUBLICATIONS

Refereed Publications

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Letters

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Book Chapters and Invited Papers

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4. **Moorman PG**, Terry PD. Dairy products and breast cancer. 2003. United Kingdom Dairy Council. (Invited paper)
5. **Moorman PG**, Berchuck A. Comment on: Hormone replacement therapy does not increase risk for ovarian cancer in women with BRCA mutations. *North American Menopause Society First to Know*. Feb. 15, 2006. www.menopause.org/news.html.
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Technical Reports

1. **Moorman PG**, Goldstein K, Coeytaux R, Myers ER, Strauss J, Van Houtven C, Shepherd-Banigan M, Brancu M, Von Isenberg M, Van Noord M, Conklin J, Lallinger K, Schmidt R, McBroom Brooks A, Sanders-Schmidler G. Topic Brief: Nutritional needs of older women. Prepared for Office of Women's Health and Agency for Healthcare Research Quality (AHRQ), 2017.
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Non-authored Publications (acknowledged for contributions)

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Presentations and Published Abstracts (selected)

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Moorman PG. Menopausal hormones and risk of breast cancer. Carolina Breast Cancer Study Participant Symposium, Chapel Hill, NC, April 2000

Moorman PG, Jones BA, Millikan RC, Hall IJ, Newman B. Race, anthropometric factors, and stage at diagnosis of breast cancer. Society for Epidemiologic Research, Seattle, WA, June 2000.

Hall IJ, Newman B, Millikan RC, **Moorman PG**. Comparative analysis of breast cancer risk factors among African-American women and white women. Congress of Epidemiology, Toronto, Ontario, Canada, June 2001.

Moorman PG, et al. Nuts and bolts of field studies: things they didn't teach you in school. Congress of Epidemiology, Toronto, Ontario, Canada, June 2001. (Invited talk)

Moorman PG, Calingaert B, Vine M, Halabi S, Berchuck A, Schildkraut JM. Comparison of two methods for calculating lifetime ovulatory cycles. Congress of Epidemiology, Toronto, Ontario, Canada, June 2001.

Plummer P, Jackson S, Konarski J, Mahanna E, Dunmore C, Regan G, Mattingly D, Parker B, Williams S, Andrews C, Vannappagari V, Hall S, Deming S, Hodgson E, **Moorman P**, Newman B, Millikan R. Making epidemiologic studies responsive to the needs of participants and communities: the Carolina Breast Cancer Study experience. Conference on Breast Cancer and Environmental Mutagens, Research Triangle Park, NC, September 2001.

Moorman PG. Population-based study of breast cancer among African-American and White women in North Carolina. North Carolina Central University, Durham, NC, January 2003. (Invited talk)

Moorman PG. Medication use and breast cancer risk. Psychiatry and Behavioral Sciences Grand Rounds, Memorial Sloan-Kettering Cancer Center, New York, NY, March 2003. (Invited talk)

Sansbury L, Millikan R, Schroeder J, **Moorman P**, North K, Sandler R. Use of non-steroidal anti-inflammatory drugs, cyclooxygenase-2 Val411Ala polymorphism and association with colon cancer in a population-based study of African Americans and whites. 3rd Annual AACR International Conference, Seattle, WA, October 2004.

Schildkraut JM, Berchuck A, Murphy S, Marks J, **Moorman P**, Calingaert B, Halabi S. Trinucleotide repeat polymorphisms in the androgen receptor gene and risk of ovarian cancer. 3rd Annual AACR International Conference, Seattle, WA, October 2004.

Moorman PG, Sesay J, Nwosu V, Millikan R. Non-steroidal anti-inflammatory drugs, COX2 polymorphism and breast cancer: a study of gene-environment interactions. Triangle Cancer and Disparities Symposium, North Carolina Central University, Durham, NC, March 2005.

Moorman PG. Racial disparities in breast cancer: problem or opportunity? Johnson C. Smith University, Charlotte, NC, September 2005. (Invited talk)

Trivers K, Gammon M, Abrahamson P, Lund MJ, Kaufman J, **Moorman P**, Cai JW, Porter P, Brinton L, Eley JW. Reproductive factors and breast cancer survival in women less than 55 years of age. 4th Annual Conference on Frontiers in Cancer Prevention Research, Baltimore, MD, November 2005.

Moorman PG. The role of epidemiology in the drug development process. University of Ferrara, Ferrara, Italy, May 2006. (Invited talk)

Moorman PG. Racial disparities in breast cancer: risk factors through survival. Women's Health Research Symposium - Untying the Pink Ribbon: Advances in Breast Cancer. University of Maryland School of Medicine. Baltimore, MD, March 2008. (Invited talk)

Moorman PG, JM Schildkraut JM, ES Iversen ES, ER Myers ER, M Gradison M1, N Warren-White N, F Wang. Weight gain after pre-menopausal hysterectomy. Society for Epidemiologic Research, Chicago, IL, June 2008.

Moorman PG. Non-steroidal anti-inflammatory drugs (NSAIDs) as chemopreventives for cancer: are they ready for prime time? Genetics and Environmental Mutagenesis Society 26th Annual Fall Meeting. Research Triangle Park, NC, October 2008. (Invited talk)

Moorman PG. Introduction to cancer epidemiology. Osher Lifelong Learning Institute lecture series. Chapel Hill, NC, September 2009. (Invited talk)

Moorman PG. Challenges of epidemiologic research in the genomic era: the example of ovarian cancer. Environmental Mutagen Society Annual Meeting, St. Louis, MO, October 2009 (Invited talk)

Moorman PG. Epidemiology in clinical research: beyond randomized controlled trials. Duke University Health System Clinical Education and Professional Development Series, Durham, NC, January 2010. (Invited talk)

Moorman PG. Epidemiology in clinical research: beyond randomized controlled trials. Association of Clinical Research Professionals, Durham, NC, June 2010. (Invited talk)

Moorman PG. The role of epidemiology in understanding disparities in breast cancer. Duke Oncology Symposium – Advances in Surgical and Treatment Options for Breast and Colorectal Cancer. Raleigh, NC, May 2011. (Invited talk)

Østbye T, **Moorman P.** Measurement dilemmas: validity, reliability and messy data. Family Medicine Research Seminar Series, Duke University Medical Center, December 2011.

Moorman P, Østbye T. Research that can tell you something: internal and external validity in study design. Family Medicine Research Seminar Series, Duke University Medical Center, November 2011.

Myers ER, Havrilesky LJ, Gierisch J, **Moorman PG**, Dinan MA, Coeytaux R, Urrutia RP, Lowery WJ, Hasselblad V, McBroom AJ, Sanders GD. Using net benefits and acceptability curves to quantify uncertainty about tradeoffs between harms and benefits of oral contraceptives. Society for Medical Decision Making, Phoenix, AZ, October 2012.

Myers ER, Havrilesky LJ, Gierisch J, **Moorman PG**, Dinan MA, Coeytaux R, Urrutia RP, Lowery WJ, Hasselblad V, McBroom AJ, Sanders GD. Net effects of current patterns of oral contraceptive use on potentially fatal outcomes in the United States. Society for Medical Decision Making, Phoenix, AZ, October 2012.

Stouder A, Melcher B, Morgan PA, **Moorman PG**, Lin L, Stem J. Satisfaction Guaranteed? An Analysis of Lecturer Characteristics Associated with Physician Assistant Student Satisfaction. Physician Assistant Education Association Annual Education Forum, Seattle, WA, November 2012.

Moorman PG. The African American Cancer Epidemiology Study (AACES). Ovarian Cancer in Women of African Ancestry Emerging Consortium Meeting. Bethesda, MD, April 2013.

Moorman PG. Ovarian Cancer: What You Need to Know. Duke Cancer Institute, Cancer Awareness Workshop. Durham, NC, May, August and October 2014.

Moorman PG. Ovarian Cancer in African American Women: The Challenges of Studying a Less Common

Cancer in a Minority Population. Duke Cancer Institute Cancer Control and Population Sciences Seminar Series. Durham, NC, July 2014.

CONSULTANT APPOINTMENTS

National Institutes of Health, Center for Scientific Review

- Epidemiology and Disease Control Subcommittee 2 (EDC-2): Oct. 2000, Feb. 2001
- Special Emphasis Panels: Nov. 2001, Mar. 2002, Nov. 2002, Nov. 2003, July 2004, Nov. 2004, June 2005, Mar. 2006, Nov. 2006, Mar. 2007, July 2007, Nov. 2008, June 2009, July 2009, July 2010, Oct. 2010, Sept. 2011, Dec. 2013, Mar. 2017, Nov. 2017
- Small Grants Program for Cancer Epidemiology: Nov. 2001, Mar. 2003, June 2016, Mar. 2017, June 2017, June 2018, Nov. 2018
- National Cancer Institute, Program Project Review: Jan. 2003, Aug. 2003, Dec. 2003.
- SPORE (Specialized Program of Research Excellence) Review: Breast Cancer Feb. 2005, Ovarian Cancer June 2008, Feb. 2009.

Centers for Disease Control and Prevention. Defining the Public Health Research Agenda for Ovarian Cancer. Invited panel participant. Nov. 2008.

Susan G. Komen for the Cure, Study Section Chair for Post-Doctoral Fellowship in Risk and Prevention, 2010.

Susan G. Komen Breast Cancer Foundation, Study Section Chair for Risk, Prevention and Epidemiology, Member of Programmatic Review Committee, 2005 – 2007.

Susan G. Komen for the Cure/Susan G. Komen Breast Cancer Foundation, Scientific Reviewer, 2003 - 2011.

Department of Defense Breast Cancer Research Program Scientific Peer Review, 1998, 2005, 2007, 2008, 2009, 2013.

Department of Defense Breast Cancer Research Program, Study Section Chair for Training - Epidemiology and Prevention, 2013.

Department of Defense Ovarian Cancer Research Program Scientific Peer Review, 2015, 2016.

Department of Defense Ovarian Cancer Research Program, Study Section Chair for Investigator Initiated Research II, 2018.

National Cancer Institute, Center for Global Health, Data Monitoring Committee for United States – Latin American Cancer Research Network, 2013

CODA, Inc., Research Triangle Park, NC. IRB member, 2004.

National Institute of Environmental Health Sciences Special Emphasis Panel, Technical Evaluation of Support Services for Epidemiology, NIEHS Epidemiology Branch. May 1998.

PROFESSIONAL AWARDS AND SPECIAL RECOGNITIONS

Honorary Physician Assistant, Duke University Medical Center Physician Assistant Program - 2018

Certificate of Appreciation, Duke University Medical Center Physician Assistant Program – 2008

Delta Omega, Public Health Honorary – 1994

The Endocrinologist, Editorial Prize for Volume II – 1993

Research Service Award, National Cancer Institute - 1988-91

Edward E. Smismann Award for Medicinal Chemistry, University of Kansas – 1980

Walter F. Enz Award for Pharmaceutical Chemistry, University of Kansas – 1980

Watkins-Berger Scholarship, University of Kansas - 1975-1980

State of Kansas Scholarship, University of Kansas - 1976-1980

ORGANIZATIONS AND PARTICIPATION

University of North Carolina School of Public Health Alumni Association, Epidemiology Section President, 2001-2002.

Society for Epidemiologic Research

American Pharmaceutical Association

TEACHING RESPONSIBILITIES

Courses Taught

Evidence Based Medicine-I, Duke University, Department of Community and Family Medicine, Physician Assistant program. Primary instructor, 2004-2017.

Evidence Based Medicine-II, Duke University, Department of Community and Family Medicine, Physician Assistant program. Co-Instructor, 2003-2018.

Evidence Based Medicine-I, Duke University, Department of Community and Family Medicine, Physician Assistant program. Lecturer and seminar instructor, 2003.

Epidemiology and Research Methods (PAP 255), Duke University, Department of Community and Family Medicine, Physician Assistant program. Seminar instructor, 2001-2002.

Epidemiology of Cancer (CDE 532B), Yale University, Department of Epidemiology and Public Health. Course director, 1997-2000.

Co-developer of departmental Master's Comprehensive Examination, University of North Carolina-Chapel Hill, Department of Epidemiology, 1995-1996.

Cancer Epidemiology (EPID 233), University of North Carolina-Chapel Hill, Department of Epidemiology, Teaching Assistant, 1992-1993.

Principles of Epidemiology (EPID 160), University of North Carolina-Chapel Hill, Department of Epidemiology, Teaching Assistant, 1990.

Student Mentoring

Helena Furberg, MSPH, University of North Carolina, 1996, Committee Member

Pamela M. Marcus, PhD, University of North Carolina, 1997, Committee Member

Stella Chang, MPH, Yale University, 1997, Committee Member
Mary Riciutti, MPH, Yale University, 1999, Committee Chair
Edward A. Lew, MPH, Yale University, 1999, Committee Member
Shelley Goodstine, MPH, Yale University, 1999, Committee Member
Rupal Desai, MPH, Yale University, 1999, Committee Member
Pei-Yu Lin, MPH, Yale University, 2000, Committee Chair
Lisa Calvocoressi, Ph.D., Yale University, 2003, Dissertation Reader
Rebecca Cleveland, Ph.D., University of North Carolina, 2003, Committee Member
Leah Sansbury, Ph.D., University of North Carolina, 2004, Committee Member
Sumitra Shantakumar White, Ph.D., University of North Carolina, 2006, Committee Member
Katrina Trivers, Ph.D., University of North Carolina, 2006, Committee Member
Amy Dailey, Ph.D., Yale University, 2006, Dissertation Reader
Enid Rivera, M.D., Duke University, 2008, 3rd year Medical Student Preceptor
Alexis Gaines, Duke University, 2013, Master's Committee Member
Chioma Erundu, Duke University, 2013-14, 3rd year Medical Student Preceptor
Tolulope Teniola, Duke University 2016-17, 3rd year Medical Student Preceptor
Tengteng Wang, University of North Carolina, 2018, Committee Member

COMMITTEES AND SERVICE

Standing Committee on Misconduct in Research, Duke University School of Medicine, 2017-present
Senior Faculty Advisory Committee, Office for Research Mentoring, Duke University School of Medicine, 2016-present
Academy of Mentors, Office of Faculty Mentoring, Duke University School of Medicine, 2014-16
Society for Epidemiologic Research. Reviewer for Tyroler and Lilienfeld Prize Papers, 2015
Appointments, Promotions and Tenure Committee, Department of Community and Family Medicine, Duke University Medical Center. Committee Member, 2008-2018
Quality Assurance Sub-Committee for Clinical Research Units, Duke University Medical Center, Committee Chair, 2013-2014
Quality Assurance Sub-Committee for Clinical Research Units (formerly Site-based Research Units), Duke University Medical Center, Committee Member, 2011-2013
Path to Independence Faculty Mentoring Program, Duke University School of Medicine, Peer Reviewer, 2012-2018
Society for Epidemiologic Research. Abstract reviewer for annual meeting, 2011
Cancer Prevention, Detection and Control Research Program, Duke University Medical Center, Cancer Control Pilot Study application reviewer, 2010, 2011

Executive Council, Department of Community and Family Medicine, Duke University Medical Center
2009-present

Education Committee, Department of Community and Family Medicine, Duke University Medical Center,
2009-2017

Faculty Search Committee, Cancer Prevention, Detection and Control Research Program, 2010

Duke Cancer Institute, Editorial Advisory Committee Member, 2010-2011

Duke Comprehensive Cancer Center Annual Meeting, Judge for poster presentations, 2009

Director Search Committee, Cancer Prevention, Detection and Control Research Program, 2009

Partners Allied in Research (PAIR) Pilot Grant application reviewer, Cancer Prevention, Detection and
Control Research Program, 2005

Editorial Reviewer

American Journal of Epidemiology
Archives of Gynecology and Obstetrics
Breast Diseases
Cancer
Cancer Causes and Control
Cancer Research
Epidemiology
Gynecologic Oncology
International Journal of Epidemiology
Journal of Community Development
J of the Women's American Medical Assn
Lancet
Nutrition and Cancer
Public Health Nutrition
Women and Health

Annals of Epidemiology
Breast Cancer Research and Treatment
British Medical Journal-Cancer
Cancer Biomarkers
Cancer Epidemiology Biomarkers and Prevention
Clinical Breast Cancer
Ethnicity and Disease
International Journal of Cancer
JAMA
Journal of the National Cancer Institute
Journal of Women's Health
Lancet Oncology
Pharmacogenomics
Trends in Molecular Medicine

CURRENT RESEARCH

Epidemiology of breast and ovarian cancer
Ovarian function after hysterectomy
Racial differences in disease risk and outcomes
Medication use and cancer risk
Etiologic factors for uterine fibroids

EXTERNAL SUPPORT - PAST

Principal Investigator	% effort	Title of Project and Funding Source	Total Costs	Duration
Barbara Hulka	25%	High-Density Lipoprotein Cholesterol and Breast Cancer, National Cancer Institute, R03, Supported dissertation research	\$72,234	1992 – 1993

Beth Newman	100%	Carolina Breast Cancer Study, Project 2 SPORE in Breast Cancer, National Cancer Institute, P50.	\$1,275,000	1992 – 1995
Beth Newman	50%	Carolina Breast Cancer Study, Project 2 SPORE in Breast Cancer, National Cancer Institute, P50.	\$2,511,146	1995 - 1996
Patricia Moorman	50%	Medication Use and Breast Cancer in a Bi-racial Population, National Cancer Institute, R29-FIRST Award.	\$498,302	1996 – 2002
Patricia Moorman	0%	Carolina Breast Cancer Study Participant Symposium, North Carolina Division of American Cancer Society Small Grant.	\$2500	1997
Patricia Moorman	0%	Carolina Breast Cancer Study Participant Symposium, Susan G. Komen Breast Cancer Foundation Small Grant.	\$5000	1997
Joellen Schildkraut	10%	Carolina Georgia Center, Cancer Genetics Network, National Cancer Institute, U-24.	\$4,028,129	2002 – 2004
Patricia Moorman	0%	Non-steroidal Anti-Inflammatory Drugs and Breast Cancer: A Study of Gene-Environment Interactions among African-American and White Women, Minority Serving Institution Partnership Grant, Pilot Funds.	\$28,040	2003 – 2004
Celette Skinner	5%	Partnerships to Eliminate Disparities in Cancer Outcomes and Research, National Cancer Institute, National Cancer Institute.	\$517,743	2002 – 2006
Patricia Moorman	0%	Diversity Supplement to RO1 AG020162 Ovarian Failure Among Hysterectomized Women, National Institute on Aging (Note: Grant was awarded but post-doc accepted another position.)	\$169,720	2006
Andrew Berchuck	5%	Biological Basis for Chemoprevention of Ovarian Cancer, Department of Defense.	\$824,000	2002 – 2007
Stephen Freedland	5%	Weight Loss and Gain and Cancer Free Survival after Radical Prostatectomy in a Multiethnic Cohort. Prostate Cancer Foundation.	\$100,000	2007-2009
Joellen Schildkraut	10%	Genetic Modifiers of BRCA1 and BRCA2, Project 3 SPORE in Breast Cancer. National Cancer Institute.	\$1,795,862	2003 – 2009
Joellen Schildkraut	10%	Molecular Epidemiology of Ovarian Cancer. National Cancer Institute.	\$3,750,000	2003 – 2010

Patricia Moorman	40%	Ovarian Failure among Hysterectomized Women. National Institute on Aging.	\$3,781,480	2003 - 2010
Patricia Moorman (Sub-contract PI)	3%	Cancer Genetics Network. National Cancer Institute.	~\$25,000	2010 – 2012
Laura Havrilesky	15%	Oral Contraceptive Use for the Primary Prevention of Ovarian Cancer. Agency for Healthcare Research and Quality	\$486,476	2010 - 2012
Jeffrey Marks	5%	Atlantic Breast and Gynecologic Clinical Validation Center. National Cancer Institute	>\$1,500,000	2010 - 2013
Cathrine Hoyo	5%	Disparities in Cervical Cancer Precursors and Deregulation of Imprinted Genes National Cancer Institute	~\$200,000	2012 – 2013
Emanuel Trabuco (Moorman, Duke PI)	2%	Anti-Müllerian Hormone as a Marker of Ovarian Reserve in Women with and without Hysterectomy. Mayo Clinic Internal Funds	\$100,000	2012 – 2013
Evan Myers	10%	Systematic Review of Cancer Screening Literature for Updating American Cancer Society Breast Cancer Screening Guidelines American Cancer Society	~\$400,000	2013 - 2014
Joellen Schildkraut	9%	Cancer Education and Career Development Training Grant. National Cancer Institute	~\$1,400,000	2009 – 2014
Patricia Moorman (Sub-contract PI)	5%	Rare Cancer Genetics Network National Cancer Institute	~\$240,000	2010 – 2016
Joellen Schildkraut (Moorman, co-PI)	20%	Epidemiology of Ovarian Cancer in African American Women National Cancer Institute	~\$12,000,000	2010 – 2017
Gillian Sanders	10%	Management of Infertility Evidence-Based Practice Center		2015-2016
Gillian Sanders	10%	Management of Labor Dystocia Evidence-Based Practice Center		2016
Gillian Sanders	15%	Office of Women’s Health – Topic Development Evidence-Based Practice Center		2016
Evan Myers	5%	Comparing Management Options for Management: Patient-centered Results for Uterine Fibroids (COMPARE-UF) PCORI	~\$19,000,000	2014 – 2018

EXTERNAL SUPPORT - CURRENT

Principal Investigator	% effort	Title of Project and Funding Source	Total Costs	Duration
Joellen Schildkraut (Moorman, sub-contract PI)	13%	Exploring Factors Related to Racial Disparities in Ovarian Cancer Incidence and Survival: The OCWAA (Ovarian Cancer in Women of African Ancestry) Consortium National Cancer Institute	~\$450,000	2017 - 2021

PERSONAL INFORMATION

Work address: DUMC Box 2715, 2424 Erwin Road, Suite 602, Durham, NC 27705

Work phone #: (919) 681-4557

E-mail address: patricia.moorman@duke.edu

Home address: 3 Skipwith Court, Durham, NC 27707

Home phone #: (919) 419-9301

Marital status: Married

Spouse's name: Allan R. Moorman, Ph.D.

Exhibit 23

Patricia Moorman, Ph.D., M.S.P.H.

Page 1

IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI

GAIL INGHAM, ET AL.,)	
)	
Plaintiffs,)	
)	
vs.)	Case No.
)	1522-CC10417-01
JOHNSON & JOHNSON, ET AL.,)	Division 10
)	
Defendants.)	
_____	/	

DEPOSITION OF PATRICIA MOORMAN, Ph.D., M.S.P.H.

(Taken by Defendants)

Durham, North Carolina

Monday, March 12, 2018

Reported in Stenotype by
Amy A. Brauser, RPR, RMR, CRR
Transcript produced by computer-aided transcription

Patricia Moorman, Ph.D., M.S.P.H.

<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES</p> <p>2 ON BEHALF OF THE PLAINTIFFS:</p> <p>3 STEVE FARIES, ESQUIRE</p> <p>4 The Lanier Law Firm</p> <p>5 6810 Cypress Creek Parkway</p> <p>6 Houston, Texas 77069</p> <p>7 (713) 659-5200</p> <p>8 steve.faries@lanierlawfirm.com</p> <p>9</p> <p>10 ON BEHALF OF THE DEFENDANTS JOHNSON & JOHNSON AND</p> <p>11 JOHNSON & JOHNSON CONSUMER COMPANIES INC., NOW KNOWN</p> <p>12 AS JOHNSON & JOHNSON CONSUMER INC.:</p> <p>13</p> <p>14 MARK HEGARTY, ESQUIRE</p> <p>15 Shook, Hardy & Bacon, LLP</p> <p>16 2555 Grand Boulevard</p> <p>17 Kansas City, Missouri 64108</p> <p>18 (816) 474-6550</p> <p>19 mhegarty@shb.com</p> <p>20 ON BEHALF OF THE DEFENDANT IMERY'S TALC AMERICA, INC:</p> <p>21 MICHAEL R. KLATT, ESQUIRE</p> <p>22 Gordon & Rees, LLP</p> <p>23 816 Congress Avenue, Suite 1510</p> <p>24 Austin, Texas 78701</p> <p>25 (512) 391-0197</p> <p>mkclatt@grsm.com</p> <p>ON BEHALF OF THE WITNESS:</p> <p>JEFF GIBSON, ESQUIRE</p> <p>Cohen & Malad, LLP</p> <p>One Indiana Square, Suite 1400</p> <p>Indianapolis, Indiana 46032</p> <p>(317) 636-6481</p> <p>jgibson@cohenandmalad.com</p> <p>ALSO PRESENT:</p> <p>Michelle A. Parfitt</p>	<p style="text-align: right;">Page 4</p> <p>1 INDEX OF EXAMINATIONS</p> <p>2 By Mr. Hegarty. Page 8, 344, 355</p> <p>3 By Mr. Klatt. Page 290, 359</p> <p>4 By Mr. Faries. Page 353</p> <p>5</p> <p>6</p> <p>7 INDEX OF EXHIBITS</p> <p>8 NUMBER DESCRIPTION MARKED/IDENTIFIED</p> <p>9 Exhibit 1 Plaintiff's Disclosure of 16</p> <p>10 Expert Testimony</p> <p>11 Exhibit 2 CV of Patricia Moorman, 19</p> <p>12 Ph.D., M.S.P.H.,</p> <p>13 Exhibit 3 Reliance Materials of Patricia 19</p> <p>14 Moorman, Ph.D.</p> <p>15 Exhibit 4 April 1, 2014, letter from FDA 86</p> <p>16 to Samuel Epstein</p> <p>17 Exhibit 5 NCI PDQ Screening and 94</p> <p>18 Prevention Editorial Board</p> <p>19 Exhibit 6 Ovarian, Fallopian Tube, and 96</p> <p>20 Primary Peritoneal Cancer</p> <p>21 Prevention (PDQ)- Health</p> <p>22 Professional Version</p> <p>23 Exhibit 7 IARC Monographs on the 105</p> <p>24 Evaluation of Carcinogenic</p> <p>25 Risks to Humans</p>
<p style="text-align: right;">Page 3</p> <p>1 DEPOSITION OF PATRICIA MOORMAN, Ph.D.,</p> <p>2 M.S.P.H., a witness called on behalf of Defendant,</p> <p>3 before Amy A. Brauser, Notary Public, in and for the</p> <p>4 State of North Carolina, at Cambria Hotel & Suites</p> <p>5 Durham, 2306 Elba Street, Durham, North Carolina, on</p> <p>6 Monday, the 12th day of March, 2018, commencing at</p> <p>7 9:01 a.m.</p> <p>8 *****</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 5</p> <p>1 INDEX OF EXHIBITS (con't)</p> <p>2 Exhibit 8 Supplemental Selenium May 147</p> <p>3 Decrease Ovarian Cancer Risk in</p> <p>4 African-American Women</p> <p>5 Exhibit 9 Analgesic Medication Use and 149</p> <p>6 Risk of Epithelial Ovarian</p> <p>7 Cancer in African-American Women</p> <p>8 Exhibit 10 Dietary Quality and Ovarian 151</p> <p>9 Cancer Risk in African-American</p> <p>10 Women</p> <p>11 Exhibit 11 Socioeconomic Status in Relation 154</p> <p>12 to the Risk of Ovarian Cancer in</p> <p>13 African-American Women: A</p> <p>14 Population-Based Case-Control</p> <p>15 Study</p> <p>16 Exhibit 12 Ovarian Cancer Risk Factors 159</p> <p>17 in African-American and White</p> <p>18 Women</p> <p>19 Exhibit 13 Primary Peritoneal and Ovarian 167</p> <p>20 Cancers: An Epidemiological</p> <p>21 Comparative Analysis</p> <p>22 Exhibit 14 Racial/Ethnic Differences in 174</p> <p>23 the Epidemiology of Ovarian</p> <p>24 Cancer: A Pooled Analysis of</p> <p>25 12 Case-Control Studies</p>

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Patricia Moorman, Ph.D., M.S.P.H.

<p style="text-align: right;">Page 6</p> <p>1 INDEX OF EXHIBITS (con't)</p> <p>2 Exhibit 15 Association between Body Powder 187</p> <p>3 Use and Ovarian Cancer: The</p> <p>4 African American Cancer</p> <p>5 Epidemiology Study (AACES)</p> <p>6 Exhibit 16 Perineal Talc Exposure and 193</p> <p>7 Epithelial Ovarian Cancer Risk</p> <p>8 in the Central Valley of California</p> <p>9 Exhibit 17 Perineal Talc Exposure and 194</p> <p>10 Subsequent Epithelial Ovarian</p> <p>11 Cancer: A Case-Control Study</p> <p>12 Exhibit 18 Association Between Talc Use 196</p> <p>13 and Ovarian Cancer A</p> <p>14 Retrospective Case-Control Study</p> <p>15 in Two US States</p> <p>16 Exhibit 19 Perineal use of Talc and Risk 224</p> <p>17 of Ovarian Cancer</p> <p>18 Exhibit 20 Genital use of Talc and Risk of 230</p> <p>19 Ovarian Cancer: A Meta-analysis</p> <p>20 Exhibit 21 Genital Powder Use and Risk of 256</p> <p>21 Ovarian Cancer: A Pooled</p> <p>22 Analysis of 8,525 Cases and</p> <p>23 9,859 Controls</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 8</p> <p>1 PATRICIA GRIPKA MOORMAN, Ph.D., M.S.P.H.,</p> <p>2 having been first duly sworn to tell the truth, was</p> <p>3 examined and testified as follows:</p> <p>4 EXAMINATION</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q. Good morning, Dr. Moorman.</p> <p>7 A. Good morning.</p> <p>8 Q. Would you, please, state your full name</p> <p>9 for the record?</p> <p>10 A. Okay. My name is Patricia Gripka Moorman.</p> <p>11 Q. Dr. Moorman, who is your current employer?</p> <p>12 A. Duke University.</p> <p>13 Q. Duke University in Durham, North Carolina?</p> <p>14 A. Yes, that's correct.</p> <p>15 Q. We are here today in Durham, North</p> <p>16 Carolina, correct?</p> <p>17 A. Yes, that is correct.</p> <p>18 Q. How long have you been employed by Duke</p> <p>19 University?</p> <p>20 A. I have -- for almost 18 years.</p> <p>21 Q. What is your current title at Duke?</p> <p>22 A. Professor in department of community and</p> <p>23 family medicine.</p> <p>24 Q. How does the department of community and</p> <p>25 family medicine compare to the medical school at Duke?</p>
<p style="text-align: right;">Page 7</p> <p>1 INDEX OF EXHIBITS (con't)</p> <p>2 Exhibit 22 Defendant's Johnson & Johnson 283</p> <p>3 and Johnson & Johnson Consumer</p> <p>4 Inc.'s First Amended Notice with</p> <p>5 subpoena Duces Tecum of Deposition</p> <p>6 of Patricia Moorman, Ph.D., M.S.P.H.</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 9</p> <p>1 Are they related, connected, the same thing? What's</p> <p>2 the relationship, if any?</p> <p>3 A. Okay. The department of community and</p> <p>4 family medicine is one of the departments within the</p> <p>5 School of Medicine.</p> <p>6 Q. Apart from your work at Duke, do you have</p> <p>7 any type of separate consulting business?</p> <p>8 A. No, I do not.</p> <p>9 Q. With regard to the fees you would earn,</p> <p>10 assuming that you earn fees, from testifying in this</p> <p>11 case, do they -- do those fees go to you personally?</p> <p>12 A. Yes, they do.</p> <p>13 Q. Besides your work at Duke and any fees</p> <p>14 generated in connection with your work on this case,</p> <p>15 do you have any other sources of income?</p> <p>16 A. Very occasionally I will receive like fees</p> <p>17 like from NIH or Department of Defense if I do grant</p> <p>18 reviews.</p> <p>19 Q. Besides those fees, any other sources of</p> <p>20 income?</p> <p>21 A. No.</p> <p>22 Q. What is your rate -- hourly rate or</p> <p>23 otherwise that you're charging for your testimony in</p> <p>24 this case?</p> <p>25 A. It is \$400 per hour.</p>

3 (Pages 6 to 9)

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<p>1 Q. How much have you been paid by Plaintiffs'</p> <p>2 attorneys in this case so far?</p> <p>3 A. I have not billed them yet. I have</p> <p>4 received nothing so far.</p> <p>5 Q. Have you prepared any type of invoice that</p> <p>6 you've not yet sent?</p> <p>7 A. I have not prepared an invoice.</p> <p>8 Q. Have you kept track of the amount --</p> <p>9 number of hours you have spent working on the case</p> <p>10 that we're here to talk about here today?</p> <p>11 A. Yes, I have.</p> <p>12 Q. How many hours have you spent -- I'm sorry</p> <p>13 to interrupt.</p> <p>14 A. Okay. I estimate it's approximately 50</p> <p>15 hours.</p> <p>16 Q. Would those hours include your review of</p> <p>17 materials?</p> <p>18 A. Yes, it would.</p> <p>19 Q. Would those hours include your meetings,</p> <p>20 if any, with the Plaintiffs' counsel in this case?</p> <p>21 A. Yes, it would.</p> <p>22 Q. Were you paid any type of retainer before</p> <p>23 you started working on this case?</p> <p>24 A. No, I have not.</p> <p>25 Q. What is your business address at Duke?</p>	<p>1 Q. Who contacted you?</p> <p>2 A. I was contacted by Mr. Faries.</p> <p>3 Q. Was this a contact by telephone?</p> <p>4 A. Let's see. I'm -- we had -- the first</p> <p>5 time I met him was in-person meeting.</p> <p>6 Q. Before that, was the meeting set up by</p> <p>7 telephone?</p> <p>8 A. I don't recall if it was telephone or</p> <p>9 e-mail.</p> <p>10 Q. So was this a situation where you had had</p> <p>11 no prior contact with Mr. Faries?</p> <p>12 MR. HEGARTY: Did I say that right?</p> <p>13 MR. FARIES: Faries, like the Ferris</p> <p>14 wheel. It just doesn't look that way.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q. Mr. Faries or any attorney for the</p> <p>17 Plaintiffs in this case? Was this a call or an e-mail</p> <p>18 out of the blue, so to speak?</p> <p>19 MR. FARIES: Objection to form.</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q. You can answer.</p> <p>22 MR. FARIES: Just -- just answer the best</p> <p>23 that you recall.</p> <p>24 THE WITNESS: No, it wasn't a call "out of</p> <p>25 the blue."</p>
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<p>1 A. My business address is Box 2715,</p> <p>2 2424 Erwin Road, Suite 602, Durham, North Carolina</p> <p>3 27705.</p> <p>4 Q. Dr. Moorman, we're here today to take your</p> <p>5 deposition in the case of Ingham, et al., versus J&J,</p> <p>6 et al. Do you understand that?</p> <p>7 A. Yes, I do.</p> <p>8 Q. Do you know where that case is pending?</p> <p>9 A. Yes, in Missouri.</p> <p>10 Q. Do you know where in Missouri?</p> <p>11 A. I believe St. Louis.</p> <p>12 Q. Have you ever been to the city of</p> <p>13 St. Louis?</p> <p>14 A. Yes, I have.</p> <p>15 Q. When's the last time you've been there?</p> <p>16 A. Probably at least five years ago.</p> <p>17 Q. Are you aware that you've been designated</p> <p>18 as a testifying expert in the Ingham case?</p> <p>19 A. Yes, I am.</p> <p>20 Q. When were you first contacted about</p> <p>21 possibly serving as an expert witness in the Ingham</p> <p>22 case?</p> <p>23 A. It was in December of 2017.</p> <p>24 Q. So less than four months ago?</p> <p>25 A. Yes.</p>	<p>1 BY MR. HEGARTY:</p> <p>2 Q. Do you know how the contact or the</p> <p>3 communication came about?</p> <p>4 A. I have talked with Mr. Gibson and</p> <p>5 Mr. Gibson made the contact.</p> <p>6 Q. Who is Mr. Gibson with?</p> <p>7 A. He is with the law firm Cohen & Malad.</p> <p>8 Q. Had you had contact with him prior to</p> <p>9 hearing from Mr. Faries either by e-mail or by</p> <p>10 telephone?</p> <p>11 A. Yes, I have.</p> <p>12 Q. When have you had contact with Mr. Gibson?</p> <p>13 MR. FARIES: Okay, hang on. I'm going to</p> <p>14 object to that question, that this witness is</p> <p>15 not authorized to speak of communications or</p> <p>16 activities she's had with other law firms. She</p> <p>17 is not a disclosed as a -- she's never testified</p> <p>18 or had a report or anything of that matter with</p> <p>19 any other firms so that is off limits for her</p> <p>20 deposition today.</p> <p>21 MR. HEGARTY: Fair enough.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. Dr. Moorman, are you aware if you've been</p> <p>24 designated to testify as an expert in any other case</p> <p>25 besides the Ingham case?</p>

4 (Pages 10 to 13)

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<p>1 A. I'm -- I'm not sure of the -- what do you 2 mean by "designated"? 3 Q. Let me -- let me ask it a different way. 4 A. Okay. 5 Q. Are you aware if you've been disclosed in 6 some formal way as a testifying expert in any case 7 other than the case we're here to talk about today, 8 the Ingham case? 9 A. Yes, I believe so. 10 Q. Do you know what other case you've been 11 disclosed as a testifying expert in? 12 A. I do not know the name of the plaintiff in 13 that case. 14 Q. Do you know where that case is pending? 15 A. Not precisely. 16 Q. Do you know the attorneys for the 17 plaintiffs in that other case? 18 A. Yes. 19 Q. Who are they? 20 A. Michelle Parfitt and Jeff Gibson. 21 Q. It's your understanding, though, that 22 you've actually been formally disclosed in some sort 23 of court document as a testifying expert in that other 24 case? 25 A. I believe so, but I am not absolutely</p>	<p>1 BY MR. HEGARTY: 2 Q. As far as your work in this case, though, 3 you understand that that connection was with 4 Mr. Faries beginning back in December, correct? 5 A. That is correct. 6 Q. With regard to that initial contact or 7 communication with Mr. Faries, do you recall when it 8 was you agreed to serve as a testifying expert in the 9 Ingham case? 10 A. I believe that was in December. 11 Q. Do you recall the date of that 12 communication or contact? 13 A. Not the exact date, no, I do not. 14 (EXHIBIT NUMBER 1 WAS MARKED FOR IDENTIFICATION) 15 BY MR. HEGARTY: 16 Q. Dr. Moorman, I'm going to mark as Exhibit 17 Number 1 a pleading filed by Plaintiffs entitled 18 Plaintiffs' Disclosure of Expert Testimony. Would you 19 take a look at Exhibit Number 1, in particular if you 20 could turn over to page 9 of that exhibit where it 21 refers to you, and first of all, tell me whether 22 you've ever seen this disclosure prior to right now? 23 MR. FARIES: Are you referring to just her 24 piece or the whole document? 25 MR. HEGARTY: Fair point.</p>
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<p>1 sure. 2 Q. Do you recall when that disclosure was? 3 A. No, no, I do not. 4 Q. Do you know when you started working with 5 Mr. Gibson in connection with that other case in which 6 you have been disclosed in? 7 MR. FARIES: Okay, hang on. I object to 8 that question. Obviously, the witness doesn't 9 know whether she's been disclosed or not, she 10 doesn't know what that means, and you -- you 11 know that there has been no Rule 26 Disclosure 12 for Ms. Moorman or any other plaintiff expert in 13 the MDL talc litigation. So this witness is not 14 here to discuss whatever she has going on with 15 other lawyers and other firms. 16 MR. KLATT: Well, she has been disclosed 17 in a publicly filed document in the MDL. 18 MR. FARIES: That is not a Rule 26 19 Disclosure. That was a letter to -- to the 20 court on a list of experts that the plaintiffs 21 in the MDL are just so-called working with. It 22 is not a -- clearly not a Rule 26 Disclosure and 23 was never intended to be so. 24 MR. HEGARTY: We'll come back to that. 25</p>	<p>1 BY MR. HEGARTY: 2 Q. Can you tell me whether you've ever seen 3 the paragraph under your name before right now? 4 A. I have seen it very recently. 5 Q. When you say "very recently," can you be 6 more precise? 7 A. Within the last week. 8 Q. Would it be a correct statement, then, 9 that you did not write the paragraph on page 9 that is 10 below your name? 11 A. That is correct. 12 Q. When you reviewed -- or let me strike 13 that. 14 Is everything in your disclosure, the 15 paragraph under your name on page 9, correct and 16 accurate? 17 A. It is not exactly as I would have written 18 it and some minor points. Okay. So in the first 19 sentence it says that I am and have been the principal 20 investigator of a number of ovarian cancer studies. I 21 think it's important to kind of qualify that. I have 22 been the principal investigator on a subcontract for 23 these studies. I have been the -- an investigator on 24 a number of ovarian cancer studies, but the overall PI 25 for these studies is someone else.</p>

5 (Pages 14 to 17)

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<p style="text-align: right;">Page 18</p> <p>1 Q. When you say "these studies," what studies 2 are you referring to? 3 A. I'm referring to the African-American 4 Cancer Epidemiology Study and also I'm currently 5 funded on a study called the -- it's a consortium, 6 Ovarian Cancer in Women of African Ancestry. 7 Q. Who -- who is the principal investigator 8 in the African-American study? 9 A. That is Joellen Schildkraut and -- okay. 10 Q. The next sentence is not accurate, is it? 11 A. No, it is not. 12 Q. The study that is referenced there is not 13 a meta-analysis; is that correct? 14 A. That is correct. 15 Q. So that's a mistake, right? 16 A. Yes. 17 Q. The study designated there, entitled 18 there, Association Between Body Powder Use and Ovarian 19 Cancer: The African-American Cancer Epidemiology 20 Study, is a retrospective case-control study, correct? 21 A. Yes, it is. 22 Q. Is there any other part of that disclosure 23 that needs clarifying or correction? 24 A. No. 25 Q. Besides pointing out that the study we</p>	<p style="text-align: right;">Page 20</p> <p>1 BY MR. HEGARTY: 2 Q. -- exhibit and would you look at it and 3 tell me whether you've seen that document before 4 today? 5 (WITNESS REVIEWS DOCUMENT) 6 A. Yes, I have seen it. 7 Q. When did you first see this document, 8 Exhibit Number 3? 9 A. Within the last week, a few days ago. 10 Q. Did you prepare Exhibit Number 3? 11 A. No, I did not. 12 Q. Do you know who prepared it? 13 A. It was prepared by Mr. Faries or his firm. 14 Q. Did you review Exhibit Number 3 before it 15 was finalized, so to speak, and when it was in draft 16 form? 17 A. He showed it to me and no changes were 18 made so . . . 19 Q. Did you have a chance to review it? 20 A. Yes. 21 Q. Is it accurate? In other words, does 22 Exhibit Number 3 contain the materials that you rely 23 upon for purposes of your opinions in this case? 24 MR. FARIES: Objection to form. 25 Just answer the best that you can.</p>
<p style="text-align: right;">Page 19</p> <p>1 referenced is not a meta-analysis that you are not the 2 principal investigator on the African-American study, 3 is there anything else that you feel that needs to be 4 clarified or explained better than this paragraph sets 5 out? 6 A. No. 7 Q. You also brought with you today a copy of 8 your CV which I'm marking as Exhibit Number 2. 9 (EXHIBIT NUMBER 2 WAS MARKED FOR IDENTIFICATION) 10 BY MR. HEGARTY: 11 Q. Would you look at Exhibit Number 2 and 12 tell me whether that is a copy of your curriculum 13 vitae and whether it is the current copy? 14 A. Yes, it is my CV, and yes, it is a current 15 copy. 16 Q. Thank you. 17 (EXHIBIT NUMBER 3 WAS MARKED FOR IDENTIFICATION) 18 BY MR. HEGARTY: 19 Q. Plaintiffs' counsel provided to us in 20 advance of your deposition what I'm marking as Exhibit 21 Number 3 which is a document entitled, Reliance 22 Materials of Patricia Moorman, Ph.D., produced March 23 5, 2018. I'm going to hand you a copy of that -- 24 MR. FARIES: Thank you. 25</p>	<p style="text-align: right;">Page 21</p> <p>1 THE WITNESS: Okay. It is -- my opinion 2 is based on documents as well as the knowledge 3 that I have acquired over more than two decades 4 as an epidemiologist. 5 BY MR. HEGARTY: 6 Q. For purposes of the opinions that you 7 intend to offer, and we'll get to those here shortly, 8 do you rely on all of the materials set out in Exhibit 9 Number 3? 10 MR. FARIES: Objection to form. 11 MR. HEGARTY: You can answer. 12 MR. FARIES: Just answer the best that you 13 can. 14 THE WITNESS: Could you repeat the 15 question? 16 BY MR. HEGARTY: 17 Q. Sure. 18 A. Again. 19 Q. For purposes of the opinions that you 20 intend to offer in this case that we'll get to here 21 shortly, do you rely on all of the materials that are 22 identified in Exhibit Number 3? 23 MR. FARIES: Same objection. 24 THE WITNESS: Okay. I am not entirely 25 sure what you mean by the term "rely" in this</p>

6 (Pages 18 to 21)

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<p>1 context. I consider these materials so . . .</p> <p>2 Okay.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. In forming your opinions for purposes of</p> <p>5 this case, are there materials in Exhibit Number 3</p> <p>6 that are more important to you than others?</p> <p>7 MR. FARIES: Objection to form.</p> <p>8 THE WITNESS: I consider everything. I --</p> <p>9 I think that peer-reviewed literature is</p> <p>10 weighted more heavily in my opinion than, for</p> <p>11 example, some of the internal documents or even</p> <p>12 testimony.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q. Are you able to look at Exhibit Number 3</p> <p>15 and identify particular studies that are the most</p> <p>16 important to you for purposes of your opinions in this</p> <p>17 case?</p> <p>18 MR. FARIES: Objection to form.</p> <p>19 THE WITNESS: No, I consider all of them.</p> <p>20 My opinion is based on a full body of</p> <p>21 literature, and I would not say that any are</p> <p>22 more important or less important. The whole</p> <p>23 body of literature is important.</p> <p>24 BY MR. HEGARTY:</p> <p>25 Q. You mentioned that you rely on your</p>	<p>1 BY MR. HEGARTY:</p> <p>2 Q. I'll give you a little bit of the basis or</p> <p>3 a reason for that question which is, this is our</p> <p>4 chance to understand your opinions and -- and be</p> <p>5 prepared, then, to follow up on those opinions when it</p> <p>6 comes time to trial and to do that we want to make</p> <p>7 sure that we have the opportunity to -- to -- for you</p> <p>8 to list the materials that you primarily rely on or</p> <p>9 will cite, call out, in -- for purpose of your</p> <p>10 opinion. So what -- my question was really to make</p> <p>11 sure that if there's anything that should be on the</p> <p>12 reliance list that we received that's not, that I</p> <p>13 wanted to have those materials identified here today.</p> <p>14 Do you understand that?</p> <p>15 MR. FARIES: Objection to form. It's</p> <p>16 impossible to understand that.</p> <p>17 MR. HEGARTY: Fair point.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. With that background, are there any other</p> <p>20 materials that you're aware of sitting here today that</p> <p>21 should be on the reliance list that are not?</p> <p>22 MR. FARIES: Objection to form and already</p> <p>23 asked and answered several times.</p> <p>24 MR. HEGARTY: You can answer.</p> <p>25 MR. FARIES: Try one more time. Give the</p>
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<p>1 experience as well -- as well as what's listed in</p> <p>2 Exhibit Number 3. Do you recall saying that or</p> <p>3 something to that effect?</p> <p>4 A. Yes.</p> <p>5 Q. In terms of, though, documents that you</p> <p>6 intend to rely upon for purposes of your opinions in</p> <p>7 this case, are there any such documents that are not</p> <p>8 included in Exhibit Number 3?</p> <p>9 MR. FARIES: Objection to form.</p> <p>10 THE WITNESS: Once again, could you repeat</p> <p>11 the question?</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. Sure. For purposes of your opinions in</p> <p>14 this case, do you intend to rely on materials,</p> <p>15 documents, studies, et cetera, that are not referenced</p> <p>16 in Exhibit Number 3?</p> <p>17 MR. FARIES: Objection to form.</p> <p>18 THE WITNESS: Okay. Again, how you are</p> <p>19 using the term "rely," I am not entirely sure of</p> <p>20 that. I do not believe that I am going to</p> <p>21 specifically cite other references, but, you</p> <p>22 know, I consider -- I consider references here</p> <p>23 and, again, things that I might have knowledge</p> <p>24 of from my years of working as an</p> <p>25 epidemiologist.</p>	<p>1 best answer that you can.</p> <p>2 THE WITNESS: Okay. I am -- cannot think</p> <p>3 of anything right offhand that I would add to</p> <p>4 the reliance list.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q. With regard to the materials on the</p> <p>7 reliance list, did you gather all these materials</p> <p>8 yourself?</p> <p>9 A. No.</p> <p>10 Q. How were they gathered?</p> <p>11 A. Different ways. The peer-reviewed</p> <p>12 articles, those would have arisen from a literature</p> <p>13 search that I would have performed. Some of the</p> <p>14 internal documents, some of the transcripts, for</p> <p>15 example, those would -- not some of them, all of them,</p> <p>16 would have been provided by the attorneys.</p> <p>17 Q. Which attorneys provided you the company</p> <p>18 documents in the transcripts or litigation reports on</p> <p>19 the back page?</p> <p>20 A. Those were provided to me by Mr. Gibson or</p> <p>21 Ms. Parfitt.</p> <p>22 Q. When did they provide those materials to</p> <p>23 you?</p> <p>24 A. I don't recall exactly. Probably, at</p> <p>25 least a year ago for most of them.</p>

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<p>1 Q. You mentioned that with regard to</p> <p>2 peer-reviewed articles you believe that -- that they</p> <p>3 were identified through a literature search by you.</p> <p>4 Were any peer-reviewed articles provided to you by</p> <p>5 counsel for Plaintiffs?</p> <p>6 A. Yes, I -- may I go back just a moment,</p> <p>7 looking at these --</p> <p>8 Q. You're looking at the last page of</p> <p>9 Exhibit 3?</p> <p>10 A. Right, the last page of Exhibit 3. Some</p> <p>11 of those documents were provided to me by Mr. Faries.</p> <p>12 Okay.</p> <p>13 Q. Can you identify which of the documents on</p> <p>14 the last page of Exhibit 3 were provided to you by</p> <p>15 Mr. Faries?</p> <p>16 A. The last three, I believe, were provided</p> <p>17 by Mr. Faries.</p> <p>18 Q. Going back to my question just before</p> <p>19 that, were any of the peer-reviewed articles that are</p> <p>20 listed in Exhibit Number 3 provided to you by counsel</p> <p>21 for Plaintiffs?</p> <p>22 A. Mr. Gibson and Ms. Parfitt provided me</p> <p>23 with some of these, they provided me with materials,</p> <p>24 but they were, in essence, everything that I had -- I</p> <p>25 was aware of already.</p>	<p>1 that.</p> <p>2 If we take out the company documents and</p> <p>3 the litigation materials on the back page and just</p> <p>4 look at the peer-reviewed articles, had you reviewed</p> <p>5 all of those peer-reviewed articles before being</p> <p>6 contacted to serve as an expert for Plaintiffs in this</p> <p>7 case?</p> <p>8 A. No.</p> <p>9 Q. Are you able to -- if we had time and we</p> <p>10 may come back to it, could you go through this list,</p> <p>11 if I asked you to, and identify the articles you had</p> <p>12 not reviewed before being contacted by Plaintiffs'</p> <p>13 counsel in this case?</p> <p>14 A. I don't think that I would be able to do</p> <p>15 that.</p> <p>16 Q. Fair enough.</p> <p>17 Is it your belief that with regard to the</p> <p>18 peer-reviewed literature in Exhibit Number 3 that</p> <p>19 the -- Exhibit Number 3 includes all of the literature</p> <p>20 that's in the public domain with regard to talc and</p> <p>21 ovarian cancer?</p> <p>22 MR. FARIES: Objection to form.</p> <p>23 I'm sorry. When I object, you can still</p> <p>24 answer --</p> <p>25 THE WITNESS: Okay.</p>
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<p>1 Q. Were these other materials, perhaps the</p> <p>2 peer-reviewed literature provided to you by Mr. Gibson</p> <p>3 and Ms. Parfitt, also provided to you at the same time</p> <p>4 they provided you the transcripts and other documents</p> <p>5 on the back page?</p> <p>6 A. Yes.</p> <p>7 Q. You mentioned you did your own research.</p> <p>8 Was this through a PubMed search, some other type of</p> <p>9 search like that?</p> <p>10 A. A PubMed search is the -- the typical</p> <p>11 basis for doing a literature search, and in any type</p> <p>12 of review of the literature, that would be a starting</p> <p>13 point. Sometimes other articles are identified in</p> <p>14 different ways, for example, reviewing articles cited</p> <p>15 by some of the papers you uncovered.</p> <p>16 Q. Is that how you did the search in this</p> <p>17 case?</p> <p>18 A. Yes.</p> <p>19 Q. Did anyone assist you in doing the</p> <p>20 literature searches?</p> <p>21 A. No.</p> <p>22 Q. Did anyone help you pick out articles to</p> <p>23 review for purposes of your opinions in this case?</p> <p>24 A. No.</p> <p>25 Q. Had you read all of the articles -- strike</p>	<p>1 MR. FARIES: -- to the best you can.</p> <p>2 THE WITNESS: Okay. Once again, if you</p> <p>3 wouldn't mind repeating the question.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. Sure. Is it your belief that Exhibit</p> <p>6 Number 3, as far as peer-reviewed literature, contains</p> <p>7 all of the articles there are in the public domain</p> <p>8 regarding talc and ovarian cancer?</p> <p>9 MR. FARIES: Objection to form.</p> <p>10 THE WITNESS: I would say probably not.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. Were there articles that you reviewed that</p> <p>13 concern talc and ovarian cancer that are not listed on</p> <p>14 Exhibit Number 3?</p> <p>15 A. No, I don't believe so.</p> <p>16 Q. Why is it your belief that Exhibit</p> <p>17 Number 3 doesn't include all of the articles in the</p> <p>18 public domain about talc and ovarian cancer?</p> <p>19 A. Okay. It reflects my expertise and what I</p> <p>20 was asked to do. I am an epidemiologist. I have no</p> <p>21 doubt that there may be literature in other fields</p> <p>22 that may be relevant to this that I do not have the</p> <p>23 expertise in, so it may be either more lab science</p> <p>24 types of articles, possibly material sciences, and so</p> <p>25 I feel that I have reviewed all of the epidemiologic</p>

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<p style="text-align: right;">Page 30</p> <p>1 literature, but I did -- cannot say with complete 2 assurance that I have reviewed all of the literature 3 related to talc and ovarian cancer. 4 Q. With regard to the materials listed in 5 Exhibit Number 3, did you review the entirety of all 6 of them? 7 A. I have looked at all of them. Okay. Some 8 of them are clearly in more detail than others. 9 Q. With regard to just the peer-reviewed 10 literature, did you review every page of every article 11 listed? 12 A. Probably not. 13 Q. With regard to the company documents that 14 are listed on page 15 of 16, did you review the 15 entirety of all of those documents? 16 A. I looked at them and really did not give a 17 lot of weight to them. I didn't read them in great 18 detail. It was somewhat hard to put them into 19 context, and so I -- I saw them, but I just didn't 20 weight them heavily at all in my opinions. 21 Q. Did you review all of the materials listed 22 on the last page in their entirety, in other words, 23 read every page? 24 A. No, I did not. 25 Q. Did you review the entirety of any of the</p>	<p style="text-align: right;">Page 32</p> <p>1 the case-control studies with regard to whether 2 there's an association between talc use and ovarian 3 cancer? 4 MR. FARIES: Objection to form. 5 THE WITNESS: I have read all of the 6 meta-analyses. Some of them are not restricted 7 to case-control studies. Some include both 8 cohort studies as well as case-control studies. 9 BY MR. HEGARTY: 10 Q. With regard to the cohort studies, have 11 you read all of the cohort studies that have looked at 12 talc use and ovarian cancer? 13 MR. FARIES: Objection to form. 14 THE WITNESS: Yes, I have. 15 BY MR. HEGARTY: 16 Q. With regard to the meta-analysis, the 17 case-control studies, the cohort studies, have you 18 carefully assessed the strengths and weaknesses of all 19 of those studies? 20 MR. FARIES: Objection to form. 21 THE WITNESS: Yes, I believe that I have. 22 BY MR. HEGARTY: 23 Q. Before making any conclusions or drawing 24 any opinions with regard to the epidemiologic studies 25 concerning talc use and ovarian cancer, do you agree</p>
<p style="text-align: right;">Page 31</p> <p>1 materials cited on the last page of Exhibit Number 3? 2 A. I have read most of these articles -- or 3 most of these documents to some extent intentionally. 4 I did not, you know -- because I wanted the opinions 5 that I offered to be my opinions, I intentionally 6 tried not to really delve into some of these 7 transcripts, you know, dissecting every word or every 8 page. 9 Q. Have you read all of the case-control 10 studies, population based and hospital based, 11 regarding whether there is an association between 12 genital talc use and ovarian cancer? 13 MR. FARIES: Objection to form. 14 THE WITNESS: I believe that I have. 15 BY MR. HEGARTY: 16 Q. Do you -- have you concluded any 17 particular papers with regard to the case-control 18 studies that are more important to you than others? 19 MR. FARIES: Objection to form. 20 THE WITNESS: As I have replied 21 previously, I'm considering the entire body of 22 literature, it's important to do that, and so 23 all of them are important to make my opinion. 24 BY MR. HEGARTY: 25 Q. Have you read all of the meta-analysis of</p>	<p style="text-align: right;">Page 33</p> <p>1 that it's important to account for bias, chance, and 2 confounding in those studies? 3 A. Whenever I review the scientific 4 literature, it's always important to consider 5 potential sources of bias. 6 Q. Before reaching any opinions or 7 conclusions about talc and ovarian cancer, do you 8 agree that it would be important to look at the entire 9 body of literature on the subject? 10 MR. FARIES: Objection to form. 11 THE WITNESS: Once again, could you, 12 please? 13 BY MR. HEGARTY: 14 Q. Sure. Before coming to any opinions with 15 regard to talc and ovarian cancer and their 16 relationship, do you agree that it's -- it would be 17 important to look at the entire body of literature 18 that looks at talc and ovarian cancer? 19 MR. FARIES: Objection to form. 20 THE WITNESS: Okay. If I'm understanding 21 your question correctly, you're asking me should 22 I review the epidemiologic literature as well as 23 literature that may be in fields that are 24 somewhat far afield from my expertise. 25</p>

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<p>1 BY MR. HEGARTY: 2 Q. Well, I'm not sure that's exactly it, but 3 the entire body of literature as I would define it 4 would include animal studies, cell studies, other 5 medical studies in addition to the epidemiologic 6 literature. Do you feel like it would be important to 7 review all of that literature as it relates to talc 8 and ovarian cancer before drawing any conclusions 9 about the association, if any, between talc and 10 ovarian cancer? 11 MR. FARIES: Objection to form. 12 THE WITNESS: I think that it is important 13 to consider other literature while also 14 recognizing where my expertise is. 15 BY MR. HEGARTY: 16 Q. Well, did you review all of the animal 17 studies that have looked at the effect of talc? Let 18 me strike that. 19 Have you reviewed all the animal studies 20 that have looked at the effects of talc on those 21 animals? 22 A. I have looked at some of the animal 23 studies that have looked at the effects of talc. That 24 is not my area of expertise so -- my primary area of 25 expertise so I cannot say with certainty that I have</p>	<p>1 again, I am an epidemiologist, I am not a cancer or 2 cell biologist so . . . 3 Q. Can you name any of the studies that have 4 examined whether talc is genotoxic? 5 A. Once again, the authors I can't name off 6 the top of my head. 7 Q. Have you looked at studies exploring 8 whether talc is mutagenic to cells? 9 A. I have not examined studies in detail for 10 the same reason as I've described previously. 11 Q. Have you examined or reviewed studies that 12 have looked at whether talc is cytotoxic? 13 A. Once again, these are all studies in the 14 realm of cell biology, cancer biology, and I have not 15 reviewed them in detail because of my expertise. 16 Q. Are you an expert in whether talc is 17 genotoxic? 18 A. No, I would not consider myself an expert. 19 Q. Do you consider yourself an expert in the 20 cell or animal studies looking at talc and ovarian 21 cancer? 22 A. No, I do not consider myself an expert 23 there. 24 Q. Are you an expert in the studies that have 25 looked at whether talc is mutagenic or cytotoxic?</p>
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<p>1 reviewed all of the animal studies. 2 Q. Can you name any of the animal studies 3 where animals have been exposed and then the effects 4 looked at? 5 A. I cannot recall the names of the authors. 6 Q. Are you aware that cell studies have been 7 done where ovarian cancer cells have been exposed to 8 talc? Are you aware of that? 9 A. I am aware that some studies have been 10 done. 11 Q. Have you reviewed all of the cell studies 12 that have looked at the effects of talc on ovarian 13 cancer cells? 14 A. Once again, that is an area that is 15 outside my area of expertise. I have seen some of 16 them. I have not done a comprehensive review of those 17 studies. 18 Q. Can you name any of those studies, sitting 19 here today? 20 A. I can -- off the top of my head, I cannot 21 name the authors. 22 Q. Have you reviewed studies looking at 23 whether talc is genotoxic? 24 A. I have looked at some studies that have 25 discussed whether or not it is genotoxic, but once</p>	<p>1 A. No, I do not consider myself. 2 Q. Have you examined all of the studies 3 looking at whether talc can migrate or be transported 4 from the perineum to the ovaries? 5 MR. FARIES: Objection to form. 6 THE WITNESS: I have looked at several of 7 them. I've -- I have reviewed all that I'm 8 aware of. 9 BY MR. HEGARTY: 10 Q. So Exhibit Number 3 would include all of 11 the migration or translocation studies with regard to 12 talc to the ovaries that you're aware of; is that 13 correct? 14 A. I think so, but I'm not absolutely sure. 15 Q. Do you consider yourself an expert in 16 whether talc can migrate or translocate from the 17 perineum to the ovaries? 18 A. Okay. I consider myself an expert in the 19 epidemiology of ovarian cancer. These particular 20 studies I would not necessarily consider myself an 21 expert. 22 Q. In looking back again at Exhibit Number 3, 23 the very last list of testimony that's cited there, 24 are you aware that there are tens of other expert 25 transcripts besides those listed on the back page of</p>

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<p style="text-align: right;">Page 38</p> <p>1 Exhibit Number 3? Are you aware of that?</p> <p>2 A. I assume that there would be others, but I</p> <p>3 can't say that I knew that with certainty.</p> <p>4 Q. There is one transcript of a Defense</p> <p>5 expert on the back page of Exhibit Number 3. Are you</p> <p>6 aware that there are tens of other transcripts of</p> <p>7 Defense experts?</p> <p>8 A. I -- again, I do not know specifically,</p> <p>9 but I certainly made the assumption that there were</p> <p>10 other transcripts than these.</p> <p>11 Q. Did you ever ask counsel for Plaintiffs to</p> <p>12 provide you transcripts or reports of Defense experts</p> <p>13 in this litigation?</p> <p>14 A. No, I did not.</p> <p>15 Q. Did you have any interest in reviewing the</p> <p>16 transcripts or Defense report -- or -- or reports of</p> <p>17 the Defense experts in this litigation?</p> <p>18 A. As I have said previously, I tried to form</p> <p>19 the opinions based on my review of the literature</p> <p>20 rather than basing it on someone else's opinions.</p> <p>21 Q. If we look at the second-to-last page of</p> <p>22 Exhibit Number 3, there is a listing of Bates numbers</p> <p>23 which are company documents which we spoke about a</p> <p>24 moment ago. Do you actually rely on any of the</p> <p>25 company documents listed on this page for your</p>	<p style="text-align: right;">Page 40</p> <p>1 documents that have been provided in this case by J&J</p> <p>2 and by Imerys?</p> <p>3 A. As I said, I don't know the volume of</p> <p>4 documents. I assume that there would be others.</p> <p>5 Q. Did you ask to review any other company</p> <p>6 documents besides those listed in Exhibit Number 3?</p> <p>7 A. I did not.</p> <p>8 Q. Why didn't you?</p> <p>9 A. I felt that my charge was to provide an</p> <p>10 opinion in my area of expertise, the epidemiology of</p> <p>11 ovarian cancer, and so I felt that the best way to do</p> <p>12 that was to rely on the published literature, the</p> <p>13 peer-reviewed literature.</p> <p>14 Q. There was a protective order that was</p> <p>15 entered in the Ingham case with regard to review of</p> <p>16 company documents. Did you sign that protective order</p> <p>17 before you reviewed the company documents?</p> <p>18 A. I believe that I did.</p> <p>19 Q. Did -- for purpose of your opinions in</p> <p>20 this case, did you do any of your own testing to</p> <p>21 support those opinions?</p> <p>22 MR. FARIES: Objection to form.</p> <p>23 THE WITNESS: Can you tell me what you</p> <p>24 mean by "testing"?</p> <p>25</p>
<p style="text-align: right;">Page 39</p> <p>1 opinions in this case?</p> <p>2 MR. FARIES: Objection to form.</p> <p>3 THE WITNESS: As I said before, I gave</p> <p>4 these a cursory readthrough. I found it</p> <p>5 somewhat difficult to put them into context.</p> <p>6 They were over large period of time and so I</p> <p>7 looked at them, I said, okay, there's some</p> <p>8 information, but it was not something that I</p> <p>9 weighed heavily in my opinion.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q. This list was not a list of documents that</p> <p>12 you put -- you provided. Let me strike that, that's</p> <p>13 not -- that's a bad question.</p> <p>14 The materials listed here as far as Bates</p> <p>15 numbered documents were provided to you by Plaintiffs'</p> <p>16 counsel, correct?</p> <p>17 A. That is correct.</p> <p>18 Q. Are you aware that there are millions of</p> <p>19 other pages of company documents that have been</p> <p>20 produced in this litigation?</p> <p>21 A. I don't know the volume of it, the</p> <p>22 millions of pages, I assume that, yes, there were many</p> <p>23 other documents.</p> <p>24 Q. But do you understand that these documents</p> <p>25 represent a tiny fraction of the total number of</p>	<p style="text-align: right;">Page 41</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. Sure. Did you do any of your own number</p> <p>3 crunching or meta-analysis or your own analysis of the</p> <p>4 data besides what was listed in the published medical</p> <p>5 literature?</p> <p>6 A. I did not perform a meta-analysis on my</p> <p>7 own.</p> <p>8 Q. Did you reanalyze any of the data that's</p> <p>9 contained in any of the peer-reviewed literature that</p> <p>10 you reviewed?</p> <p>11 A. No, I did not.</p> <p>12 Q. Did you come here today prepared to</p> <p>13 provide to us the opinions that you intend to offer in</p> <p>14 this case?</p> <p>15 A. Yes, I did.</p> <p>16 Q. Can you tell me those opinions?</p> <p>17 A. Okay. My primary opinion is that based on</p> <p>18 the body of scientific literature that with a</p> <p>19 reasonable degree of scientific certainty that women</p> <p>20 who have used talcum powder products are at higher</p> <p>21 risk for ovarian cancer than women who did not use</p> <p>22 them.</p> <p>23 Q. Any other opinions that you intend to</p> <p>24 offer in this case?</p> <p>25 MR. FARIES: Objection to form.</p>

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<p>1 THE WITNESS: Okay. That is my</p> <p>2 overarching opinion and it is supported by my</p> <p>3 review of the literature.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. And to your knowledge, do you intend to</p> <p>6 offer any other "overarching" opinions besides that</p> <p>7 opinion?</p> <p>8 MR. FARIES: Objection to form.</p> <p>9 THE WITNESS: I will offer, perhaps, other</p> <p>10 opinions in support of that primary opinion.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. Are there any other primary opinions,</p> <p>13 though, besides that one?</p> <p>14 A. I -- that is my primary opinion, yes.</p> <p>15 Q. With regard to your primary opinion, as it</p> <p>16 relates to women who are exposed to talc versus those</p> <p>17 who are not exposed to talc, are your opinions that</p> <p>18 the talc that's at issue is contaminated with</p> <p>19 asbestos?</p> <p>20 A. My opinion is, I'm basing it on exposure</p> <p>21 to talcum powder products and that it is possible that</p> <p>22 there are other constituents in the powder other than</p> <p>23 just than -- other than just talc.</p> <p>24 Q. Do you intend to offer the opinion in this</p> <p>25 case that J&J's baby powder and Shower to Shower</p>	<p>1 what you mean?</p> <p>2 A. Okay. As I formulated my opinion, as I'm</p> <p>3 sure you are aware, in epidemiology we often consider</p> <p>4 the work of Austin Bradford Hill. He laid out some</p> <p>5 considerations that scientists should reasonably</p> <p>6 consider as they're trying to form an opinion about</p> <p>7 causality. Okay. Not -- these are not criteria that</p> <p>8 have to be checked off, but they kind of lead one</p> <p>9 through a careful consideration of several, I think</p> <p>10 that he terms them viewpoints that should be taken</p> <p>11 into account. And so I did consider what are</p> <p>12 potential biologically plausible mechanisms for this</p> <p>13 exposure and this outcome that we're considering.</p> <p>14 Q. Do you agree that there is talcum powder</p> <p>15 that is asbestos-free?</p> <p>16 MR. FARIES: Objection to form.</p> <p>17 THE WITNESS: I -- I am not a mineral</p> <p>18 scientist and so I could not say that with</p> <p>19 certainty.</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q. Is it your opinion that all talcum powder</p> <p>22 products are contaminated with asbestos?</p> <p>23 A. I, once again, not a mineral scientist who</p> <p>24 has analyzed all talcum powder products so to say -- I</p> <p>25 do not think that it is appropriate to give the</p>
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<p>1 products have asbestos in them?</p> <p>2 MR. FARIES: Objection to form.</p> <p>3 THE WITNESS: Okay. As I have had</p> <p>4 discussions with Mr. Faries, he has asked me to</p> <p>5 consider if there is, in fact, evidence of other</p> <p>6 constituents, including asbestos, in the talcum</p> <p>7 powder, how that would shape my opinion.</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q. What was your response to that question?</p> <p>10 A. My response was that I -- I could consider</p> <p>11 it as I formulated my opinion.</p> <p>12 Q. And did you consider it in formulating</p> <p>13 your opinions for this case?</p> <p>14 A. Yes, I did.</p> <p>15 Q. And what was the nature of that</p> <p>16 consideration?</p> <p>17 A. It comes into play in relation to the</p> <p>18 biological plausibility of this exposure and this</p> <p>19 outcome.</p> <p>20 Q. Did you draw any -- let me back up.</p> <p>21 Did you analyze for purposes of your</p> <p>22 opinions in this case biologic plausibility of talc</p> <p>23 and ovarian cancer?</p> <p>24 A. I considered biological plausibility, yes.</p> <p>25 Q. When you say "considered," can you tell me</p>	<p>1 absolutes as you just laid out, either all or none.</p> <p>2 Q. Do you have an opinion as to whether --</p> <p>3 strike that.</p> <p>4 Do you -- do you have an opinion you</p> <p>5 intend to offer in this case that all talcum powder</p> <p>6 products have asbestos contamination?</p> <p>7 A. Once again, I would not offer the opinion</p> <p>8 that "all" have asbestos contamination. I would</p> <p>9 refrain from, as I said, the absolutes, all of them do</p> <p>10 or none of them do.</p> <p>11 Q. But do you intend to offer the opinion</p> <p>12 that J&J's baby power and Shower to Shower products</p> <p>13 over the years have been contaminated with asbestos?</p> <p>14 A. I will offer the opinion that I think that</p> <p>15 there is some evidence that some of their products</p> <p>16 have had asbestos contamination.</p> <p>17 Q. What evidence is that?</p> <p>18 A. In the literature it is commonly stated</p> <p>19 that there was asbestos contamination of talc</p> <p>20 products, particularly prior to 1976, but there has</p> <p>21 also been some published literature as well as some</p> <p>22 documents provided to me by the attorney that</p> <p>23 suggest -- or that indicates that products since that</p> <p>24 time period are not asbestos-free.</p> <p>25 Q. With regard to the literature, did any of</p>

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<p>Page 46</p> <p>1 the -- the literature specifically refer to Johnson's</p> <p>2 baby powder and Johnson's Shower to Shower products?</p> <p>3 A. I actually don't recall that level of</p> <p>4 detail. I recall it being described as talcum powder.</p> <p>5 Q. With regard to the documents that you</p> <p>6 mentioned in addition to that literature, are those</p> <p>7 the documents that you received that are included in</p> <p>8 Exhibit Number 3?</p> <p>9 MR. FARIES: Oh, I'm sorry.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. Have you reviewed all of the testing</p> <p>13 documents that J&J's provided in this case with regard</p> <p>14 to the analysis of its talcum powder products?</p> <p>15 A. No, I have not.</p> <p>16 Q. In fact, have you reviewed any testing</p> <p>17 documents beyond those, if any, that are referenced in</p> <p>18 Exhibit Number 3?</p> <p>19 A. No, I have not.</p> <p>20 Q. Do you understand that J&J has produced</p> <p>21 tens of thousands of testing documents in this case?</p> <p>22 A. Once again, I don't know the volume of</p> <p>23 documents that J&J has produced.</p> <p>24 Q. Do you intend to offer the testimony that</p> <p>25 J&J's baby powder and Shower to Shower products have</p>	<p>Page 48</p> <p>1 MR. FARIES: Objection to form.</p> <p>2 THE WITNESS: No.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. Do you feel that you've done enough work</p> <p>5 to verify that assumption?</p> <p>6 MR. FARIES: Objection to form.</p> <p>7 THE WITNESS: To take that assumption, it</p> <p>8 was not the full basis of my opinion, but I</p> <p>9 think that I saw enough to say that this was an</p> <p>10 opinion with at least some scientific basis,</p> <p>11 that it was not just pulled out of thin air.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. Besides asbestos, did you make -- were you</p> <p>14 told to make an assumption of any other constituents</p> <p>15 within talcum powder products?</p> <p>16 A. The primary assumption was based on</p> <p>17 asbestos.</p> <p>18 Q. Going back to your primary opinion, is it</p> <p>19 your opinion that women who are exposed to -- or</p> <p>20 strike -- strike that.</p> <p>21 Is it your primary -- is it your opinion</p> <p>22 that women who use talcum powder products without</p> <p>23 asbestos are at a higher risk of ovarian cancer than</p> <p>24 women who did not use them?</p> <p>25 MR. FARIES: Objection to form.</p>
<p>Page 47</p> <p>1 had asbestos in them without reviewing all of the</p> <p>2 testing documents that have been produced in this</p> <p>3 case?</p> <p>4 MR. FARIES: Objection to form.</p> <p>5 THE WITNESS: There will be -- my -- it is</p> <p>6 my understanding that there will be other</p> <p>7 experts who are experts in mineral analysis</p> <p>8 and -- and testing that will be testifying in</p> <p>9 this case and I would anticipate that they will</p> <p>10 have done a much more thorough review of it. I</p> <p>11 was -- my opinion here, as I stated previously,</p> <p>12 was based, in part, on Mr. Faries asking me to</p> <p>13 make an assumption that some baby powders -- or</p> <p>14 some talcum powder products do contain</p> <p>15 constituents other than talc including asbestos.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. Have you done anything yourself to verify</p> <p>18 that assumption?</p> <p>19 A. Okay. I have, again, read peer-reviewed</p> <p>20 literature that indicates that that is not an</p> <p>21 unreasonable assumption.</p> <p>22 Q. Anything besides the peer-reviewed</p> <p>23 literature and the review of the company documents</p> <p>24 identified in Exhibit Number 3 to verify that</p> <p>25 assumption?</p>	<p>Page 49</p> <p>1 THE WITNESS: Okay. My opinion is that</p> <p>2 the studies on which I am basing my opinion, the</p> <p>3 epidemiologic studies, it is not possible to</p> <p>4 distinguish asbestos-containing talc products</p> <p>5 from talc products that might not contain</p> <p>6 asbestos, and so I don't think that it is</p> <p>7 possible with the data I have to make that</p> <p>8 distinction. However, I do think that there is</p> <p>9 biologically plausible reasons to expect that</p> <p>10 talc could lead to ovarian cancer even if there</p> <p>11 were no asbestos contained in it.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. Going back to your primary opinion, is it</p> <p>14 your opinion that women who use talcum powder products</p> <p>15 that do not contain asbestos do have a higher risk of</p> <p>16 ovarian cancer than women who do not?</p> <p>17 MR. FARIES: Objection to form.</p> <p>18 THE WITNESS: Okay. Once again, as I</p> <p>19 answered just a moment ago, we do not have that</p> <p>20 data in the epidemiologic studies. There is no</p> <p>21 way -- when women report their use of talcum</p> <p>22 powder products, there is no way for us to say,</p> <p>23 Did this talcum powder contain asbestos or not.</p> <p>24 BY MR. HEGARTY:</p> <p>25 Q. So you would not be able to -- so you</p>

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<p>1 would not have the opinion, because you said you can't</p> <p>2 have the opinion because the data is not there, that</p> <p>3 women who use talcum powder without asbestos have a</p> <p>4 higher risk of ovarian cancer than women who do not,</p> <p>5 correct?</p> <p>6 A. Please repeat that one more time.</p> <p>7 Q. Sure. Based on what you said, it cannot</p> <p>8 be your opinion, then, that women who use talcum</p> <p>9 powder products without asbestos are at a higher risk</p> <p>10 of ovarian cancer than women who do not use such</p> <p>11 talcum powder products, correct?</p> <p>12 MR. FARIES: Objection to form.</p> <p>13 THE WITNESS: My opinion is based on</p> <p>14 talcum powder products and the women in the</p> <p>15 studies that I considered, we -- we don't know.</p> <p>16 They're -- women who use talcum powder, they</p> <p>17 don't know, was there asbestos in it or not.</p> <p>18 They just reported that they used talcum powder</p> <p>19 products. So my opinion is based on the use of</p> <p>20 talcum powder products.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q. So would -- is it correct, then, that you</p> <p>23 don't know whether women who use talcum powder</p> <p>24 products without asbestos are at a higher risk of</p> <p>25 ovarian cancer than women who don't use such products?</p>	<p>1 A. Exactly.</p> <p>2 Q. There are eight other Bradford Hill</p> <p>3 factors, correct?</p> <p>4 A. Correct.</p> <p>5 Q. Have you analyzed all of the Bradford Hill</p> <p>6 factors besides biologic plausibility with regard to</p> <p>7 the risk of talc without asbestos in ovarian cancer?</p> <p>8 MR. FARIES: Objection to form.</p> <p>9 THE WITNESS: The -- the answer remains</p> <p>10 the same. We are analyzing data that is based</p> <p>11 on women reporting talcum powder products.</p> <p>12 Okay. And those data -- those are -- the data</p> <p>13 that were analyzed, those are the data that I</p> <p>14 considered. It can only be based on the talcum</p> <p>15 powder products. It cannot be based on whether</p> <p>16 talc didn't -- talc without asbestos or talc</p> <p>17 with asbestos because it's based just on the</p> <p>18 reporting of the talcum powder product.</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q. Is there any data out there that has</p> <p>21 looked at the risk of ovarian cancer with just talcum</p> <p>22 powder without asbestos?</p> <p>23 MR. FARIES: Objection to form.</p> <p>24 THE WITNESS: I -- I feel like you're</p> <p>25 asking me the same question again and again.</p>
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<p>1 MR. FARIES: Objection to form, asked and</p> <p>2 answered.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. You can answer.</p> <p>5 MR. FARIES: You can repeat what you've</p> <p>6 already said and then we'll move on.</p> <p>7 THE WITNESS: Okay. Again, women have</p> <p>8 reported on talcum powder products and my</p> <p>9 opinion is based on women who use talcum powder</p> <p>10 products. They had no way of knowing, did the</p> <p>11 products that they used contain asbestos or did</p> <p>12 not. Okay. My opinion is based on the use of</p> <p>13 the products that they reported.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. Have you analyzed any -- strike that.</p> <p>16 Have you developed any opinions on whether</p> <p>17 talcum powder without asbestos increases the risk of</p> <p>18 ovarian cancer?</p> <p>19 A. Okay. My opinion is that there are</p> <p>20 biologically plausible reasons to -- to think that</p> <p>21 talc could lead to an increased risk of ovarian cancer</p> <p>22 even if there was no asbestos contamination.</p> <p>23 Q. Understood.</p> <p>24 That's -- biologic plausibility is one of</p> <p>25 the Bradford Hill factors, correct?</p>	<p>1 All of the epidemiologic studies are asking</p> <p>2 about talcum powder product use. The women</p> <p>3 would not have been able to -- to say this was</p> <p>4 without asbestos or with asbestos. It's based</p> <p>5 on talcum powder use.</p> <p>6 MR. FARIES: Mark, can we take a break</p> <p>7 now?</p> <p>8 MR. HEGARTY: Yeah.</p> <p>9 MR. FARIES: Been going a little over an</p> <p>10 hour.</p> <p>11 THE WITNESS: Okay.</p> <p>12 (RECESS TAKEN FROM 10:04 A.M. TO 10:20 A.M.)</p> <p>13 MR. HEGARTY: We're back on the record.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. Dr. Moorman, going back to your primary</p> <p>16 opinion, is it your opinion -- is it going to be your</p> <p>17 opinion in this case that talcum powder products cause</p> <p>18 ovarian cancer?</p> <p>19 A. Yes, it will be.</p> <p>20 Q. And if I were to ask you the same</p> <p>21 questions I asked you about talc without asbestos,</p> <p>22 your answers -- as I did when I asked you about talc</p> <p>23 increasing the risk, your answers would be the same,</p> <p>24 correct?</p> <p>25 MR. FARIES: Objection to form.</p>

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<p>1 THE WITNESS: I would say -- repeat the 2 question, please. 3 BY MR. HEGARTY: 4 Q. Sure. If I ask you the same series of 5 questions about talc without asbestos as it relates to 6 your primary opinion about talc increasing the risk of 7 ovarian cancer in users versus nonusers, but I asked 8 those same questions as to talc causing ovarian 9 cancer, you would give me the same answers; is that 10 correct? 11 MR. FARIES: Objection to form. 12 THE WITNESS: My answer would be that 13 talcum powder products on the basis of how women 14 reported them in these studies based on the 15 entire body of literature, yes, I would say that 16 talcum powder products, it can cause ovarian 17 cancer. 18 BY MR. HEGARTY: 19 Q. If the evidence establishes that Johnson 20 baby powder and Shower to Shower have been asbestos 21 free over the years, is it correct that you would not 22 have the opinion that Johnson baby powder and Shower 23 to Shower cause ovarian cancer? 24 MR. FARIES: Objection to form. Objection 25 to the incomplete hypothetical.</p>	<p>1 Q. When I talk about the studies looking at 2 asbestos and ovarian cancer, do you understand that 3 I'm separating those out of the talcum powder products 4 looking at ovarian cancer? Do you understand that? 5 A. Yes, I do understand that. 6 Q. And do you know how many studies that have 7 looked at asbestos exposure in ovarian cancer that are 8 occupational exposures? 9 A. I do not know the exact number. I know 10 that there have been quite a few. 11 Q. Do you know if there have been any 12 nonoccupational exposure studies looking at asbestos 13 exposure in ovarian cancer? 14 A. Yes, there are studies characterized as 15 more environmental asbestos exposure. 16 Q. Can you name for me any such studies? 17 A. I cannot name the specific authors. I 18 believe that there was a study that was done in 19 Australia where women were not directly occupationally 20 exposed, but it was thought that they had exposure 21 either through inhalation exposure or, perhaps, 22 through a family member involved in the industry. 23 Q. Do you know how many total women have been 24 studied in the studies looking at asbestos exposure in 25 asbestos -- I mean, in ovarian cancer?</p>
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<p>1 BY MR. HEGARTY: 2 Q. You can answer. 3 A. Okay. My opinion is not based on -- 4 exclusively on them containing asbestos. My opinion 5 is based on the talcum powder products that the women 6 reported in our -- in the studies. 7 Q. Is it your opinion that asbestos causes 8 ovarian cancer? 9 A. Yes. 10 Q. Have you done an in-depth analysis of the 11 literature looking at asbestos exposure in ovarian 12 cancer? 13 A. I have looked at the literature related to 14 asbestos in ovarian cancer, yes. 15 Q. How many studies have looked at the 16 potential link between asbestos and ovarian cancer? 17 MR. FARIES: Objection to form. 18 THE WITNESS: I cannot give you an exact 19 answer. 20 BY MR. HEGARTY: 21 Q. Do you list all of the studies you 22 reviewed with regard to asbestos only in ovarian 23 cancer in your disclosure, Exhibit Number 3? 24 A. I don't know. I don't know. There have 25 been quite a lot of those studies.</p>	<p>1 A. I do not know the exact number. 2 Q. Are you aware of the difficulties that 3 have existed over time distinguishing between 4 peritoneal mesothelioma and ovarian cancer? 5 MR. FARIES: Objection to form. 6 THE WITNESS: I am aware that that has 7 been an issue that has been discussed in the 8 literature. 9 BY MR. HEGARTY: 10 Q. What are the difficulties in 11 distinguishing between peritoneal mesothelioma and 12 ovarian cancer? 13 MR. FARIES: Objection to form. 14 THE WITNESS: Many times ovarian cancer is 15 rather advanced when it is diagnosed, and there 16 can be some involvement throughout the 17 peritoneum, and sometimes -- so some authors 18 have indicated that it can be a little bit 19 difficult or have raised the opinion that it 20 might be difficult to distinguish between an 21 ovarian and a peritoneal. 22 BY MR. HEGARTY: 23 Q. That difficulty can lead to a 24 misclassification of cases in controls, correct? 25 A. That has been an issue discussed in the</p>

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<p>1 literature.</p> <p>2 Q. And misclassification -- such</p> <p>3 misclassification would also be called</p> <p>4 misclassification bias, correct?</p> <p>5 A. It -- yes, it is a potential bias, yes.</p> <p>6 Q. And such a potential bias can affect the</p> <p>7 results of any study looking at asbestos exposure in</p> <p>8 ovarian cancer, correct?</p> <p>9 MR. FARIES: Objection to form.</p> <p>10 THE WITNESS: Yes, we examine biases,</p> <p>11 potential biases because of our concern about</p> <p>12 how they might affect the conclusions of the</p> <p>13 study.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. And have the studies that have looked at</p> <p>16 asbestos exposure in ovarian cancer considered</p> <p>17 confounding as it relates to whether you're looking at</p> <p>18 occupational versus nonoccupational -- strike that.</p> <p>19 Let me start over again.</p> <p>20 Have there been studies looking at or</p> <p>21 trying to address confounding as an independent risk</p> <p>22 factor?</p> <p>23 MR. FARIES: Objection to form.</p> <p>24 THE WITNESS: Off the top of my head, I</p> <p>25 can't recall the extent to which they address</p>	<p>1 conclusion either -- or either the overall conclusion</p> <p>2 or the -- the strength of the association that you're</p> <p>3 looking at.</p> <p>4 Q. Would you agree that exposure to asbestos</p> <p>5 through perineal cosmetic talc use, assuming that talc</p> <p>6 has asbestos in it, is different from an occupational</p> <p>7 exposure to asbestos in a factory or in a plant?</p> <p>8 MR. FARIES: Objection to form.</p> <p>9 THE WITNESS: So you -- is exposure to</p> <p>10 asbestos in an occupational exposure different</p> <p>11 than exposure through use in talcum powder?</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. Assuming for purpose of the question that</p> <p>14 talcum powder has asbestos in it.</p> <p>15 A. Has asbestos in it.</p> <p>16 MR. FARIES: Objection to form.</p> <p>17 THE WITNESS: They are somewhat different</p> <p>18 exposures.</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q. How are they different?</p> <p>21 A. In the -- probably in the level of</p> <p>22 exposure.</p> <p>23 Q. Would you agree that studies that have</p> <p>24 looked at, for example, women working in factories</p> <p>25 where asbestos is part of the product have a different</p>
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<p>1 confounding in those studies.</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q. For example, in the talc ovarian cancer</p> <p>4 studies, a number of factors are adjusted for in those</p> <p>5 studies to address confounding, correct?</p> <p>6 A. Yes, that is very common.</p> <p>7 Q. And have the studies that have looked at</p> <p>8 asbestos exposure in ovarian cancer all accounted for</p> <p>9 or adjusted for potential confounding factors such as</p> <p>10 other risk factors for ovarian cancer?</p> <p>11 MR. FARIES: Objection to form.</p> <p>12 THE WITNESS: As I answered previously, I</p> <p>13 cannot recall in those studies the degree to</p> <p>14 which they controlled for confounding.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q. If studies don't control for confounding,</p> <p>17 again, that can lead to results that are potentially</p> <p>18 inaccurate, correct?</p> <p>19 MR. FARIES: Objection to form.</p> <p>20 THE WITNESS: If you do not control for</p> <p>21 confounding, it is a potential bias, yes.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. And a potential bias can distort the</p> <p>24 results of the study, correct?</p> <p>25 A. It can lead to making an inaccurate</p>	<p>1 level of exposure than women who use talcum powder</p> <p>2 products, assuming for the question that there is even</p> <p>3 any talc -- any asbestos in talcum powder products?</p> <p>4 MR. FARIES: Objection to form.</p> <p>5 THE WITNESS: I think that it is</p> <p>6 reasonable to assume that women who are working</p> <p>7 in an occupation that makes asbestos-based</p> <p>8 products, that they're going to have a different</p> <p>9 level of exposure than women who have -- who use</p> <p>10 talcum powder products.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. That different level of exposure would be</p> <p>13 a higher level of exposure, correct?</p> <p>14 A. In -- most likely, yes.</p> <p>15 Q. Have you made any effort to quantify the</p> <p>16 differences in exposures between the occupational</p> <p>17 studies looking at asbestos and ovarian cancer and</p> <p>18 studies looking at talcum powder products and ovarian</p> <p>19 cancer?</p> <p>20 A. I have -- I have not done that. However,</p> <p>21 I think that it is important to bear in mind that</p> <p>22 several authoritative bodies have designated that</p> <p>23 there is no safe level of asbestos exposure.</p> <p>24 Q. Is it your opinion that there is no safe</p> <p>25 level of asbestos exposure?</p>

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<p>1 A. It is my opinion.</p> <p>2 Q. And what is that opinion based on?</p> <p>3 A. My opinion is based on, as I said, several</p> <p>4 organizations: The World Health Organization, and I</p> <p>5 believe NIOSH has also indicate -- and The World Trade</p> <p>6 Organization. I believe that all of them have issued</p> <p>7 documents indicating that there is no safe level of</p> <p>8 asbestos exposure.</p> <p>9 Q. Any other authorities that you would cite</p> <p>10 to for support for your opinion that there is no safe</p> <p>11 level of asbestos exposure?</p> <p>12 A. Those are the ones that come to mind.</p> <p>13 Q. In the studies that have looked at</p> <p>14 asbestos exposure in ovarian cancer, what types of</p> <p>15 asbestos have they looked at?</p> <p>16 MR. FARIES: Objection to form.</p> <p>17 THE WITNESS: Once again, I -- I cannot</p> <p>18 recall specifically what they had looked at.</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q. What is the most common type of asbestos?</p> <p>21 MR. FARIES: Objection to form.</p> <p>22 THE WITNESS: Once again, I want to point</p> <p>23 out that I am not a mineral specialist. My</p> <p>24 understanding is that all forms of asbestos are</p> <p>25 not good for you and all should be avoided, so</p>	<p>1 which subtypes were considered.</p> <p>2 Q. Generally what had been the range of</p> <p>3 relative risks or odds ratios reported between</p> <p>4 asbestos exposure and ovarian cancer?</p> <p>5 MR. FARIES: Objection to form.</p> <p>6 THE WITNESS: You know, there have been</p> <p>7 many papers that have -- that I have looked at.</p> <p>8 All of the papers have many numbers reported in</p> <p>9 them, so it's rather hard to say precisely. It</p> <p>10 seems like most of them are in the range of</p> <p>11 standard mortality ratios around 3ish.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. Well, do you have an opinion as to the</p> <p>14 overall relative risk of ovarian cancer with talcum</p> <p>15 powder product use?</p> <p>16 A. The range, the overall --</p> <p>17 Q. Let me ask it again. Do you have a</p> <p>18 particular relative risk or odds ratio that you</p> <p>19 attribute to exposure to talcum powder products in</p> <p>20 ovarian cancer?</p> <p>21 A. Okay.</p> <p>22 MR. FARIES: Objection to form.</p> <p>23 THE WITNESS: Based on multiple</p> <p>24 meta-analyses, the summary relative risk, the</p> <p>25 overall relative risk associated with talcum</p>
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<p>1 I -- I really never considered that as I, you</p> <p>2 know, evaluated or read that literature.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. Can you name the various types of</p> <p>5 asbestos?</p> <p>6 A. Some of them.</p> <p>7 Q. Tell me the names that you know.</p> <p>8 A. Tremolite and chrysotile, and I know there</p> <p>9 are others, but I can't recall them.</p> <p>10 Q. Does the effect of various types of</p> <p>11 asbestos -- strike that.</p> <p>12 Is the risk of ovarian cancer affected by</p> <p>13 the type of asbestos to which a person is exposed to?</p> <p>14 In other words, is the risk different by -- based on</p> <p>15 subtype or subtype of asbestos?</p> <p>16 MR. FARIES: Objection to form.</p> <p>17 THE WITNESS: I don't know that any</p> <p>18 literature has actually evaluated that. I . . .</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q. How about as to subtype of ovarian cancer,</p> <p>21 is there certain subtypes of ovarian cancer that are</p> <p>22 believed more strongly linked to asbestos exposure</p> <p>23 than others?</p> <p>24 A. I don't recall in the studies that have</p> <p>25 looked at it in relation to asbestos, the extent to</p>	<p>1 powder use has been approximately 1.25, 1.3.</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q. And have you determined such a overall</p> <p>4 relative risk for asbestos exposure in ovarian cancer?</p> <p>5 A. There have been meta-analyses that have</p> <p>6 looked at that. Off the top of my head, I cannot</p> <p>7 recall the exact value.</p> <p>8 MR. FARIES: I'm sorry, can we pause for a</p> <p>9 second? I'm going to see if I can get these</p> <p>10 guys in the hallway outside just to quiet down</p> <p>11 for a sec.</p> <p>12 (DISCUSSION HELD OFF THE RECORD)</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q. The last question really went back to the</p> <p>15 previous one where I had asked you whether you</p> <p>16 formulated an opinion or came to an overall relative</p> <p>17 risk or odds ratio for talcum powder use in ovarian</p> <p>18 cancer that you then responded by saying as 1.25 to</p> <p>19 1.3. So my question was whether you've done the same</p> <p>20 thing as to the literature looking at asbestos</p> <p>21 exposure and to be more specifically, occupational</p> <p>22 asbestos exposure and ovarian cancer?</p> <p>23 MR. FARIES: Objection to form.</p> <p>24 THE WITNESS: Okay. Once again, I have</p> <p>25 read that literature, and I have read hundreds</p>

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<p>1 of papers. I cannot off the top of my head</p> <p>2 recall what the overall estimate like from --</p> <p>3 for example, meta-analyses of asbestos exposure</p> <p>4 in ovarian cancer.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q. With regard to the studies that have</p> <p>7 looked at asbestos exposure in ovarian cancer, is</p> <p>8 there a difference in overall relative risks or odd</p> <p>9 ratios between the cases that have looked at</p> <p>10 occupational exposure -- studies that have looked at</p> <p>11 occupational exposure and those studies that have</p> <p>12 looked at nonoccupational exposure? In other words,</p> <p>13 are the relative risks different between the two types</p> <p>14 of studies?</p> <p>15 MR. FARIES: Objection to form.</p> <p>16 THE WITNESS: Once again, I am having -- I</p> <p>17 cannot say with certainty what exactly they</p> <p>18 reported.</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q. Do you recall from reading your -- from</p> <p>21 your reading of the literature whether the relative</p> <p>22 risks are higher for occupational exposures versus</p> <p>23 nonoccupational exposures as it relates to asbestos</p> <p>24 and ovarian cancer?</p> <p>25 A. Once again, I cannot recall exactly the</p>	<p>1 hundreds of documents I reviewed, and some of</p> <p>2 the specific details, I believe the IARC</p> <p>3 document assessed primarily occupational</p> <p>4 exposure, that I thought that they also looked</p> <p>5 at some of the nonoccupational exposure.</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q. Do you recall the Working Group's --</p> <p>8 strike that.</p> <p>9 Do you recall the IARC monograph stating</p> <p>10 that the Working Group based its causal findings on</p> <p>11 five strongly positive cohort mortality studies of</p> <p>12 women with heavy occupational exposure to asbestos?</p> <p>13 Does that sound familiar to you?</p> <p>14 MR. FARIES: Objection to form.</p> <p>15 THE WITNESS: That sounds vaguely</p> <p>16 familiar, yes.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. Do you recall the Working Group</p> <p>19 acknowledging that an association with nonoccupational</p> <p>20 exposure was nonsignificant?</p> <p>21 MR. FARIES: Objection to form.</p> <p>22 THE WITNESS: Again, some of the specific</p> <p>23 details, it's very hard to recall all of them.</p> <p>24 I don't recall that specifically.</p> <p>25</p>
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<p>1 values reported.</p> <p>2 Q. Do you recall formulating an opinion or if</p> <p>3 you did -- strike that.</p> <p>4 Do you recall if you formulated an opinion</p> <p>5 that the literature was sufficient to establish a</p> <p>6 causal relationship between nonoccupational exposure</p> <p>7 to asbestos and ovarian cancer?</p> <p>8 MR. FARIES: Objection to form.</p> <p>9 THE WITNESS: I do not recall the</p> <p>10 literature making that distinction. I -- my</p> <p>11 overall feeling about it is that any level of</p> <p>12 asbestos exposure was to be avoided, was the</p> <p>13 overall conclusion from these studies.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. Did you review the IARC monograph on</p> <p>16 asbestos?</p> <p>17 A. Yes, I did look at that.</p> <p>18 Q. And weren't the Working Group's causal</p> <p>19 findings based on studies of women with heavy</p> <p>20 occupational exposure?</p> <p>21 MR. FARIES: Objection to form.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. Do you remember that?</p> <p>24 MR. FARIES: Sorry. Objection to form.</p> <p>25 THE WITNESS: Again, this is one of</p>	<p>1 BY MR. HEGARTY:</p> <p>2 Q. If there is a causal relationship between</p> <p>3 talcum powder product use and ovarian cancer, wouldn't</p> <p>4 you expect to find higher rates of other cancers in</p> <p>5 women using talc such as mesothelioma?</p> <p>6 MR. FARIES: Objection to form.</p> <p>7 THE WITNESS: Please repeat the question.</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q. Sure. If there was an increased risk of</p> <p>10 ovarian cancer with the use of talcum powder products,</p> <p>11 wouldn't you expect to find a higher incidence of</p> <p>12 mesothelioma in women using talcum powder products?</p> <p>13 MR. FARIES: Objection to form.</p> <p>14 THE WITNESS: I would say that is a "it</p> <p>15 depends" answer. Okay? You know, recognizing</p> <p>16 that mesothelioma is a much less common cancer</p> <p>17 than ovarian cancer, it makes it even more</p> <p>18 difficult to study. And my opinion is that it</p> <p>19 is not simply asbestos that could lead to the</p> <p>20 association between talc use -- or talcum powder</p> <p>21 products and ovarian cancer. That could be part</p> <p>22 of it, but that is not the whole thing.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. Is it your opinion that women who use talc</p> <p>25 perineally are at a greater risk of mesothelioma?</p>

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<p>1 A. I have never expressed that opinion.</p> <p>2 Q. Is it your opinion that -- or strike that.</p> <p>3 Do you have the opinion that women who use</p> <p>4 talc perineally are at a greater risk of any other</p> <p>5 type of cancer besides ovarian cancer?</p> <p>6 A. My opinion is that the evidence is</p> <p>7 inadequate to make that judgment as compared to</p> <p>8 ovarian cancer. Other cancer sites have been studied</p> <p>9 much less, and so I don't think that it is -- we can</p> <p>10 make that judgment yet.</p> <p>11 Q. Have you examined whether the literature</p> <p>12 looking at asbestos exposure in ovarian cancer shows a</p> <p>13 consistent relationship between asbestos exposure and</p> <p>14 ovarian cancer?</p> <p>15 MR. FARIES: Objection to form.</p> <p>16 THE WITNESS: So I'm thinking about the</p> <p>17 word "consistent" and how you are using that.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. Let me ask it again.</p> <p>20 A. Okay.</p> <p>21 Q. Have you done any type of analysis on</p> <p>22 whether the literature looking at asbestos exposure in</p> <p>23 ovarian cancer is consistent?</p> <p>24 A. I --</p> <p>25 MR. FARIES: Objection to form.</p>	<p>1 A. Correct.</p> <p>2 Q. My question is, having read those</p> <p>3 articles, have you formulated an opinion to a</p> <p>4 reasonable degree of scientific probability as to the</p> <p>5 mechanism by which asbestos exposure could cause</p> <p>6 ovarian cancer?</p> <p>7 A. Yes, I have an overall opinion to my level</p> <p>8 of understanding, considering that I'm not a cancer</p> <p>9 biologist.</p> <p>10 Q. What is that overall opinion?</p> <p>11 A. It seems as if the overall mechanism, in</p> <p>12 large part, can be related to chronic inflammation,</p> <p>13 and then along with the inflammatory process there are</p> <p>14 many cellular products, including the generation of</p> <p>15 reactive oxygen species, that could cause damage to</p> <p>16 DNA and ultimately lead to cancer.</p> <p>17 Q. Is that biologic mechanism dependent on</p> <p>18 the volume of fibers that -- to which the ovary is</p> <p>19 exposed?</p> <p>20 MR. FARIES: Objection to form.</p> <p>21 THE WITNESS: I do not think that it is</p> <p>22 wholly dependent on the volume of fibers.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. Is there an established number of fibers</p> <p>25 that is necessary to cause this biologic mechanism you</p>
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<p>1 THE WITNESS: I have not analyzed those</p> <p>2 data.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. Have you analyzed whether there's a dose</p> <p>5 response in the literature that has looked at asbestos</p> <p>6 exposure and ovarian cancer?</p> <p>7 A. I have not analyzed those data.</p> <p>8 Q. Have you analyzed the biologic mechanism</p> <p>9 by which asbestos exposure could cause ovarian cancer?</p> <p>10 A. I have read some about the possible</p> <p>11 biologic or the proposed plausible biological</p> <p>12 mechanism. As I stated earlier, I am not a cancer</p> <p>13 biologist, and so it seems like there are some fairly</p> <p>14 consistently reported proposed mechanisms, but, again,</p> <p>15 it is somewhat out of my area of expertise to evaluate</p> <p>16 those mechanisms.</p> <p>17 Q. Well, have you come to an opinion to a</p> <p>18 reasonable degree of scientific certainty as to the</p> <p>19 biologic mechanism by which asbestos exposure causes</p> <p>20 ovarian cancer?</p> <p>21 A. I have read papers that have laid out</p> <p>22 plausible biological mechanisms.</p> <p>23 Q. Sure. My question is a little bit</p> <p>24 different. Having read an article, you understand,</p> <p>25 doesn't mean you've formulated an opinion, correct?</p>	<p>1 just described?</p> <p>2 MR. FARIES: Objection to form.</p> <p>3 THE WITNESS: I have never read anything</p> <p>4 that would suggest that.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q. Is it your opinion that science has come</p> <p>7 to a consensus about the biologic mechanism by which</p> <p>8 asbestos exposure could cause ovarian cancer?</p> <p>9 MR. FARIES: Objection to form.</p> <p>10 THE WITNESS: I have read this mechanism</p> <p>11 in multiple papers. Inflammation from many</p> <p>12 causes is sometimes described as like a hallmark</p> <p>13 of cancer, and I think that, though, we do have</p> <p>14 to put that in context that scientific knowledge</p> <p>15 is incomplete, and so I think that this is a</p> <p>16 commonly described mechanism. I think that it</p> <p>17 may evolve as scientific knowledge evolves.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. Can asbestos exposure through inhalation</p> <p>20 cause ovarian cancer?</p> <p>21 A. Based on the literature that I've read, it</p> <p>22 does appear that that is a possible route of exposure.</p> <p>23 Q. How does asbestos -- or strike that.</p> <p>24 Is asbestos exposure to the ovaries</p> <p>25 necessary under your biological mechanism opinion, in</p>

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<p>1 other words, is it necessary that the asbestos reach 2 the ovaries for this biologic mechanism to happen? 3 MR. FARIES: Objection to form. 4 THE WITNESS: Again, recognizing that I am 5 not an overall expert in the cancer biology, my 6 understanding is that reaching the ovaries, of 7 course, is a key role, but there is also a 8 thought that generalized inflammation in the 9 body could also contribute to ovarian cancer 10 risk. 11 BY MR. HEGARTY: 12 Q. How does -- how do talc -- strike that. 13 How do asbestos fibers that are inhaled 14 reach the ovaries? 15 MR. FARIES: Objection to form. 16 THE WITNESS: My understanding is that 17 studies have shown that people who apparently 18 have only exposure through inhalation, that 19 asbestos fibers have been demonstrated in 20 multiple body parts. Some of it, I believe, is 21 potential transport through the lymphatic 22 system, but I believe that people suspect that 23 there may be other potential mechanisms as well. 24 BY MR. HEGARTY: 25 Q. Do you recall any papers that have</p>	<p>1 THE WITNESS: You are addressing a 2 hypothetical -- 3 BY MR. HEGARTY: 4 Q. Correct. 5 A. -- that is impossible. The -- every study 6 asked women to recall their use of talcum powder, and 7 in many cases it dated back decades. There would be 8 no way to test whether or not the powders that the 9 women used contained asbestos or not. So it is a 10 hypothetical -- what you're asking is hypothetical and 11 impossible. 12 Q. Well, we are allowed to ask hypotheticals. 13 A. Yeah, uh-huh. 14 Q. And my hypothetical does assume that going 15 into the study there is some -- have been some way -- 16 there's some means to have determined whether the 17 powders that were used by the women had asbestos in it 18 or not. That's an assumption in that hypothetical. 19 And if you were able to determine that, understanding 20 that we can't think of a way to do it here today, but 21 if it's possible, wouldn't the asbestos have to be 22 accounted for as a confounding factor in that study? 23 MR. FARIES: Objection to form. 24 THE WITNESS: Once again, I would not 25 consider it a confounder. I would consider it a</p>
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<p>1 described that -- any of those potential mechanisms? 2 A. Off the top of my head, I could not name a 3 specific paper. 4 Q. We talked earlier about the literature as 5 it relates to talcum powder in ovarian cancer. Is it 6 your contention that the studies that have looked at 7 talcum powder in ovarian cancer have been confounded 8 by the presence of asbestos in the talcum powder? 9 MR. FARIES: Objection to form. 10 THE WITNESS: I would not use the word 11 "confounding" in this context. I think that as 12 we have said, we -- the studies -- the 13 epidemiologic studies have looked at exposure to 14 talcum powder products, some of which may 15 contain asbestos, some may not, but we don't 16 know -- women who reported their use don't know 17 that. 18 BY MR. HEGARTY: 19 Q. Don't you agree that if in advance of the 20 study, if the scientist could determine if women -- if 21 some women in the study were exposed to talcum powder 22 with asbestos and some were not, that you would have 23 to account for that -- the presence of asbestos as a 24 confounding factor in that study? 25 MR. FARIES: Objection to form.</p>	<p>1 separate exposure, okay? So much -- if I may 2 use another example. If we are looking at 3 menopausal hormone use in relation to cancer, 4 okay, there may be different effects for 5 menopausal estrogen use versus menopausal 6 estrogen plus progestin. When you would do your 7 analysis, you would not control for progestin 8 use when you're looking at estrogen. You would 9 look at them as two distinct exposures and not 10 confounders. 11 BY MR. HEGARTY: 12 Q. So under my hypothetical, you would look 13 at -- you would compare women who had asbestos in the 14 talcum powder versus those who -- as one group, and 15 you would compare women who didn't have asbestos in 16 the talcum powder as a separate group? 17 MR. FARIES: Objection to form. 18 BY MR. HEGARTY: 19 Q. Did I say that right? 20 A. If what you described was possible, which 21 I've already stated would not be possible, one 22 would -- an epidemiologist would typically compare the 23 women who had talc with no asbestos in it, compare 24 them to women who reported no powder use, and 25 similarly they would compare the women with</p>

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<p>1 asbestos-containing talc to those with no powder use.</p> <p>2 Q. Going back to some of the review materials</p> <p>3 we talked about a little earlier, with regard to the</p> <p>4 company documents you reviewed, you had not seen any</p> <p>5 of those documents before being contacted by a</p> <p>6 Plaintiffs' counsel, correct?</p> <p>7 A. That is correct.</p> <p>8 Q. You have never worked for Johnson &</p> <p>9 Johnson, correct?</p> <p>10 A. No, I have not.</p> <p>11 Q. You've never worked for Imerys Talc</p> <p>12 America, correct?</p> <p>13 A. No, I have not.</p> <p>14 Q. Have you ever worked for any company who</p> <p>15 has manufactured or sold a talcum powder product?</p> <p>16 A. Yes.</p> <p>17 Q. Who is that?</p> <p>18 A. I was a pharmacist, and I worked in</p> <p>19 multiple drugstores over the years and all of them</p> <p>20 would have sold different types of powders.</p> <p>21 Q. Have you ever worked for a company who</p> <p>22 actually manufactured a talcum powder product?</p> <p>23 A. No, I have not.</p> <p>24 Q. Have you ever spoken to anyone at J&J or</p> <p>25 Imerys regarding their talcum powder products?</p>	<p>1 A. I really don't know.</p> <p>2 Q. Are you aware if FDA reviewed that issue,</p> <p>3 the issue of a causal link between talcum powder</p> <p>4 products and ovarian cancer back in the 1994 time</p> <p>5 frame?</p> <p>6 MR. FARIES: Objection to form.</p> <p>7 THE WITNESS: As I said previously, I</p> <p>8 don't recall the exact date when they did it.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q. Are you familiar at all with a workshop</p> <p>11 that was put together by FDA in the ISRTP back in</p> <p>12 1994?</p> <p>13 A. Not specifically, no.</p> <p>14 Q. Do you know what ISRTP stands for?</p> <p>15 A. No, I do not.</p> <p>16 Q. Are you aware of FDA evaluating two</p> <p>17 citizen petitions that sought FDA -- or that asked FDA</p> <p>18 to require warnings of ovarian cancer on talcum powder</p> <p>19 products?</p> <p>20 A. I am --</p> <p>21 MR. FARIES: Objection to form.</p> <p>22 THE WITNESS: I am aware of that.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. What did FDA conclude with regard to its</p> <p>25 analysis of those two citizen petitions?</p>
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<p>1 A. No, I have not.</p> <p>2 Q. Have you ever spoken to any company who</p> <p>3 has made a talcum powder product about their product,</p> <p>4 what's in it, anything about it?</p> <p>5 A. No, I have not.</p> <p>6 Q. Have you been involved in the development</p> <p>7 of any talcum powder product?</p> <p>8 A. No, I have not.</p> <p>9 Q. Have you ever worked directly for FDA?</p> <p>10 A. No, I have not.</p> <p>11 Q. Are you aware that FDA has looked at the</p> <p>12 issue of a causal link between talcum powder products</p> <p>13 and ovarian cancer?</p> <p>14 MR. FARIES: Objection to form.</p> <p>15 THE WITNESS: I am aware of -- that FDA,</p> <p>16 yes, has done that.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. When has FDA looked at the issue of a</p> <p>19 causal link between talcum powder products and ovarian</p> <p>20 cancer?</p> <p>21 A. I cannot say the exact date.</p> <p>22 Q. In what context did that review occur, or</p> <p>23 what was the situation that they looked at the causal</p> <p>24 link between talcum powder products and ovarian</p> <p>25 cancer?</p>	<p>1 MR. FARIES: Objection to form.</p> <p>2 THE WITNESS: I do not recall the exact</p> <p>3 conclusion that they made.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. Did you review the FDA's letter that</p> <p>6 responded to the two citizen petitions asking for</p> <p>7 warnings as to talcum powder products in ovarian</p> <p>8 cancer?</p> <p>9 A. I have read that at some point, yes.</p> <p>10 Q. Was that a letter you found on your own,</p> <p>11 or was that a letter provided to you by Plaintiffs'</p> <p>12 counsel?</p> <p>13 A. That was provided to me by the attorney.</p> <p>14 Q. Are you aware that FDA has tested consumer</p> <p>15 talc products for the presence of asbestos?</p> <p>16 A. I am aware of that.</p> <p>17 Q. Do you know when they did that?</p> <p>18 A. Once again, I do not recall the exact</p> <p>19 dates.</p> <p>20 Q. Do you recall what the results were of</p> <p>21 those tests?</p> <p>22 A. In general terms, in at least one of --</p> <p>23 the report that I recall reading, they did not</p> <p>24 identify talc in the products that they tested, but I</p> <p>25 believe that they also made the statement to the</p>

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<p>1 effect that they did not test all possible products. 2 Q. Do you recall that FDA as part of that 3 testing process did test samples of Johnson's baby 4 powder and Shower to Shower? 5 A. I don't remember specifically which 6 products they tested, once again, the many documents 7 I've read. 8 Q. Did you factor or consider -- strike that. 9 Did you consider those test results in 10 your analysis in developing your opinions in this 11 case? 12 A. As I have stated before, I read a lot of 13 papers, considered a lot of things when making my 14 opinion, and that was part of what I considered. 15 Q. Has FDA ever sought your opinions 16 regarding talcum powder -- regarding talcum powder 17 products and ovarian cancer? 18 A. No, they have not. 19 Q. You do agree that FDA has authority over 20 talcum powder products, they are authorized to 21 regulate that particular line of products? 22 MR. FARIES: Objection to form. 23 THE WITNESS: I have to say that I am not 24 absolutely certain of that. 25</p>	<p>1 analysis in this case in developing your opinions to 2 know whether FDA has designated talc as a GRAS 3 substance? 4 A. As -- 5 MR. FARIES: Objection to form. 6 THE WITNESS: As I've stated repeatedly, 7 considering all the information is important in 8 forming the opinion. 9 BY MR. HEGARTY: 10 Q. That's not something that you know one way 11 or the other? 12 A. I do -- I already told you that I do 13 not -- I did not recall anything specifically saying 14 they designated this as GRAS. 15 Q. Has FDA ever concluded there is evidence 16 of a causal relationship between genital use of talcum 17 powder products and ovarian cancer? 18 MR. FARIES: Objection to form. 19 THE WITNESS: I do not recall seeing 20 anything that they made that conclusion. 21 BY MR. HEGARTY: 22 Q. Has FDA ever required a warning of ovarian 23 cancer on talcum powder products? 24 MR. FARIES: Objection to form. 25 THE WITNESS: To my knowledge, they have</p>
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<p>1 BY MR. HEGARTY: 2 Q. Do you know what the designation GRAS 3 means, G-R-A-S? 4 A. Yes. 5 Q. What does it mean? 6 A. Going back to my pharmacy school days, I 7 recall that it was generally recognized as safe if my 8 memory serves me correctly. 9 Q. Has FDA applied that GRAS finding to talc? 10 MR. FARIES: Objection to form. 11 THE WITNESS: I do not know specifically. 12 BY MR. HEGARTY: 13 Q. Is that something you would want to know 14 for purposes of your opinions in this case? 15 MR. FARIES: Objection to form. 16 THE WITNESS: Any more information I have 17 would be the better. 18 BY MR. HEGARTY: 19 Q. Well, would it be important for purpose of 20 your opinion to look at whether FDA has designated 21 talc as a GRAS substance? 22 MR. FARIES: Objection to form. 23 THE WITNESS: Please repeat. 24 BY MR. HEGARTY: 25 Q. Sure. Would it be important for your</p>	<p>1 not. 2 BY MR. HEGARTY: 3 Q. Has any governmental agency or entity 4 anywhere in the world ever concluded that talcum 5 powder products cause ovarian cancer? 6 MR. FARIES: Objection to form. 7 THE WITNESS: I don't know in all the 8 world. I don't -- I am not aware. 9 BY MR. HEGARTY: 10 Q. Has any governmental agency anywhere in 11 the world concluded that talcum powder products 12 increase the risk of ovarian cancer? 13 MR. FARIES: Objection to form. 14 THE WITNESS: I am not aware of any that 15 have. 16 MR. FARIES: I know it hasn't been an 17 hour, but if you're about to transition, I could 18 use a comfort break. 19 MR. HEGARTY: Sure, yeah. I was going to 20 get a document out, so it might go for a little 21 bit, not long, but yeah, if you want to take a 22 break now, that's fine. 23 MR. FARIES: If you don't mind. 24 MR. HEGARTY: Take a short one. 25 (RECESS TAKEN FROM 11:05 A.M. TO 11:14 A.M.)</p>

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<p>1 (EXHIBIT NUMBER 4 WAS MARKED FOR IDENTIFICATION)</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q. Dr. Moorman, we're back on the record. We</p> <p>4 left off talking about FDA and governmental agency</p> <p>5 bodies, and I previously asked you about FDA's review</p> <p>6 of two citizen petitions. And in connection with that</p> <p>7 prior question, I'm going to hand you what I've marked</p> <p>8 as Exhibit Number 4, which is an April 1, 2014, letter</p> <p>9 from FDA to Samuel Epstein, and tell me, first of all,</p> <p>10 whether you've ever seen that letter before right now.</p> <p>11 A. I believe that I have.</p> <p>12 Q. I believe it's on your reliance list. Do</p> <p>13 you recall that?</p> <p>14 A. Yes.</p> <p>15 Q. If we look down to the second-to-last</p> <p>16 paragraph of that -- I'm sorry, you need to finish</p> <p>17 reviewing. Are you finished reviewing it?</p> <p>18 (WITNESS REVIEWS DOCUMENT)</p> <p>19 A. Okay.</p> <p>20 Q. Do you recall having read the April 1,</p> <p>21 2014, letter from FDA marked as Exhibit Number 4</p> <p>22 before right now?</p> <p>23 A. I did read it at some point, yes.</p> <p>24 Q. At some point did you read it in its</p> <p>25 entirety?</p>	<p>1 BY MR. HEGARTY:</p> <p>2 Q. And as of 2014, did you agree with FDA's</p> <p>3 position as stated in this exhibit?</p> <p>4 MR. FARIES: I'm sorry. Objection to</p> <p>5 form.</p> <p>6 THE WITNESS: Did I agree with their</p> <p>7 position?</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q. Well, let me ask it differently. As of</p> <p>10 2014 do you agree that the -- that there was not</p> <p>11 conclusive evidence of a causal association between</p> <p>12 talc use in the perineal area and ovarian cancer?</p> <p>13 MR. FARIES: Objection to form.</p> <p>14 THE WITNESS: I see that FDA did make that</p> <p>15 opinion. My opinion after reviewing the</p> <p>16 literature was not the same.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. Well, what was your opinion as to the link</p> <p>19 between talcum powder products and ovarian cancer back</p> <p>20 in 2014?</p> <p>21 A. It is very hard to say what my opinion was</p> <p>22 at any given point in time. I have considered talc as</p> <p>23 a risk factor for ovarian cancer for quite some time.</p> <p>24 I don't know at -- what my opinion specifically was at</p> <p>25 that time point, 2014.</p>
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<p>1 A. I believe that I did.</p> <p>2 Q. If you look at the first page,</p> <p>3 second-to-last paragraph from the bottom, do you see</p> <p>4 where it reads: (Reading)</p> <p>5 After careful review and</p> <p>6 consideration of the information</p> <p>7 submitted in your petitions, the</p> <p>8 comments received in response to the</p> <p>9 petitions, and review of additional</p> <p>10 scientific information, this letter is</p> <p>11 to advise you that FDA is denying your</p> <p>12 petitions. FDA did not find that the</p> <p>13 data submitted presented conclusive</p> <p>14 evidence of a causal association</p> <p>15 between talc use in the perineal area</p> <p>16 and ovarian cancer.</p> <p>17 Did I read that correctly?</p> <p>18 A. Yes, you did read that correctly.</p> <p>19 Q. You would agree that that is important</p> <p>20 information to consider on whether talcum powder use</p> <p>21 causes ovarian cancer or increases the risk of ovarian</p> <p>22 cancer, correct?</p> <p>23 MR. FARIES: Objection to form.</p> <p>24 THE WITNESS: As I have said, any</p> <p>25 information should be considered.</p>	<p>1 Q. Was it your testimony here today that back</p> <p>2 in 2014 it was your opinion that talcum powder use</p> <p>3 causes ovarian cancer?</p> <p>4 MR. FARIES: Objection to form.</p> <p>5 THE WITNESS: Once again, at any point in</p> <p>6 time, I -- it's hard to say what specifically</p> <p>7 was my opinion at that particular time point.</p> <p>8 There has been an increasing body of literature</p> <p>9 that has played into my opinion including</p> <p>10 recently published articles.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. If you turn over to the second page,</p> <p>13 second -- or last paragraph.</p> <p>14 A. Uh-huh.</p> <p>15 Q. Do you see about four lines down, the</p> <p>16 letter states: (Reading)</p> <p>17 However, large deposits of</p> <p>18 high purity, asbestos-free talc do</p> <p>19 exist, and talc purification</p> <p>20 techniques have been developed which</p> <p>21 can be used to improve talc quality.</p> <p>22 Did I read that correctly?</p> <p>23 A. Yes, you did.</p> <p>24 Q. Do you disagree with that statement?</p> <p>25 MR. FARIES: Objection to form.</p>

23 (Pages 86 to 89)

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<p>1 THE WITNESS: Once again, speaking to my 2 level of expertise, I am not a mineral 3 specialist, and so that is what they state. My 4 expertise does not allow me to agree or dispute 5 that fact. 6 BY MR. HEGARTY: 7 Q. The next line says: (Reading) 8 Thus, while it has been 9 reported in the past that cosmetic 10 talc has been contaminated with 11 asbestos, it has also been reported 12 that asbestos-free talc deposits do 13 exist. 14 Same question, do you disagree with that 15 statement? 16 MR. FARIES: Objection to form. 17 THE WITNESS: Once again, I do not have 18 the expertise in that area to agree nor 19 disagree. 20 BY MR. HEGARTY: 21 Q. Are you aware that other -- are you aware 22 if other entities or groups have made statements that 23 there are -- that talc -- that asbestos-free talc does 24 exist, are you aware that such statements have been 25 made by other entities?</p>	<p>1 BY MR. HEGARTY: 2 Q. Do you have any reason to dispute that the 3 medical doctors and scientists at FDA who were looking 4 at this evidence and who put together this analysis 5 weren't qualified to assess the safety of talc? 6 MR. FARIES: Objection to form. 7 THE WITNESS: I do not know the scientist 8 who reviewed this. I do not know their 9 qualifications, so I can't answer that. 10 BY MR. HEGARTY: 11 Q. Do you intend to offer the opinion that 12 they were not qualified to do an analysis and -- and 13 do this assessment as in Exhibit Number 4? 14 A. I am not going to offer that opinion for 15 the reasons stated. I don't know who did them, who 16 did these analyses. 17 Q. You're not -- is it also correct you're 18 not going to offer the opinion that they did not do a 19 proper job in doing this analysis and in preparing 20 that letter? 21 A. I'm not going to offer -- no, I am not 22 going to offer that opinion. 23 Q. Your reliance materials refer to the fact 24 that you reviewed as part of your analysis the NCI's 25 PDQ for ovarian cancer; is that correct?</p>
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<p>1 MR. FARIES: Objection to form. 2 THE WITNESS: I don't -- I don't know. 3 BY MR. HEGARTY: 4 Q. If you look over to the next page, do you 5 see the first line where it refers to in 2009 FDA 6 conducting an exploratory survey of currently marketed 7 cosmetic-grade raw material talc and finished cosmetic 8 products containing talc. Do you recall that -- do 9 you see that? 10 A. I do see that. 11 Q. Do you see the next paragraph begins with 12 a statement: (Reading) 13 The survey found no asbestos 14 fibers or structures in any of the 15 samples of cosmetic-grade raw material 16 talc or cosmetic products containing 17 talc. 18 Do you see that statement? 19 A. I do see that. 20 Q. Do you have any reason to disagree with 21 the accuracy of that statement? 22 MR. FARIES: Objection to form. 23 THE WITNESS: I do not have any reason to 24 disagree with that, again, going to my level of 25 expertise.</p>	<p>1 A. Yes. 2 Q. You know -- you know the NCI, correct? 3 A. Yes, I do. 4 Q. It's a highly-respected cancer research 5 institute, isn't it? 6 A. Yes, it is. 7 Q. It's the US Government's principal agency 8 for cancer research and training, correct? 9 A. Yes. 10 Q. Have you received any funding from NCI? 11 A. Yes, I have. 12 Q. Do you have any criticism of NCI? 13 MR. FARIES: Objection to form. 14 THE WITNESS: Again, can you be more 15 specific in what you mean by that question? 16 BY MR. HEGARTY: 17 Q. Well, do you have -- do you contend that 18 NCI is not capable of performing its functions? 19 MR. FARIES: Objection to form. 20 THE WITNESS: No, I do not make that 21 contention. 22 BY MR. HEGARTY: 23 Q. Do you contend that the scientists at 24 FDA -- I'm sorry, the scientists at NCI are not 25 qualified to do their jobs?</p>

24 (Pages 90 to 93)

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<p>1 A. I am not making that contention. There</p> <p>2 are many scientists there.</p> <p>3 Q. Do you understand that in preparing the</p> <p>4 NCI's PDQ, that they have a Screening and Prevention</p> <p>5 Editorial Board that's responsible for those PDQs?</p> <p>6 MR. FARIES: Objection to form.</p> <p>7 THE WITNESS: I am not specifically aware</p> <p>8 of what the process is.</p> <p>9 (EXHIBIT NUMBER 5 WAS MARKED FOR IDENTIFICATION)</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q. Let me show you what I've marked as</p> <p>12 Exhibit Number 5. I only have one copy of this.</p> <p>13 MR. FARIES: Take a quick look?</p> <p>14 MR. HEGARTY: Sure.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q. Exhibit Number 5 is a copy of the PDQ</p> <p>17 editorial board that is currently shown on the web</p> <p>18 site of the NCI. Would you look at Exhibit Number 5,</p> <p>19 Dr. Moorman, and tell me whether you know any of the</p> <p>20 individuals listed there?</p> <p>21 A. I know several of them.</p> <p>22 Q. Which ones do you know?</p> <p>23 A. Anthony Alberg is a collaborator on our</p> <p>24 AACES study. Pam Marcus went to graduate school at</p> <p>25 UNC. I was on her dissertation committee many years</p>	<p>1 board has written with regard to perineal talc</p> <p>2 exposure in ovarian cancer?</p> <p>3 A. Yes.</p> <p>4 Q. What they say is the weight of evidence</p> <p>5 does not support an association between perineal talc</p> <p>6 exposure and an increased risk of ovarian cancer,</p> <p>7 correct?</p> <p>8 MR. FARIES: I'm sorry. Objection to</p> <p>9 form. Which announcements, which year are you</p> <p>10 referring to?</p> <p>11 MR. HEGARTY: This is from the NCI web</p> <p>12 site printed off on March 1st, 2018.</p> <p>13 MR. FARIES: If you'd like the witness to</p> <p>14 review published comments, web sites, or</p> <p>15 articles, I'd ask you to please show them to</p> <p>16 her.</p> <p>17 MR. HEGARTY: Sure. If she -- if you ever</p> <p>18 want to see something, let me know. I'll mark</p> <p>19 this as Exhibit Number 6.</p> <p>20 (EXHIBIT NUMBER 6 WAS MARKED FOR IDENTIFICATION)</p> <p>21 MR. FARIES: Thank you.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. Exhibit Number 6 is the current NCI PDQ</p> <p>24 from the NCI's web site. Does that look familiar to</p> <p>25 you, Dr. Moorman?</p>
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<p>1 ago. And David Ransohoff is a faculty member at UNC</p> <p>2 that I met many years ago. And others I know by --</p> <p>3 MR. FARIES: There's more names on the</p> <p>4 back, just in case.</p> <p>5 THE WITNESS: I do not know her.</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q. I think you were about to say you know</p> <p>8 others by reputation or by some other means?</p> <p>9 A. Some I know by reputation.</p> <p>10 Q. Which ones do you know by reputation?</p> <p>11 A. Dr. Kramer, Barnett Kramer in his editor</p> <p>12 role. I know Don Berry as a statistician, some of his</p> <p>13 work.</p> <p>14 Q. To your knowledge as far as the ones you</p> <p>15 know either personally or by reputation, are they</p> <p>16 competent, respected scientists?</p> <p>17 A. Yes.</p> <p>18 Q. Do you question their ability to analyze</p> <p>19 the literature as it relates to talcum powder products</p> <p>20 and ovarian cancer and come to conclusions?</p> <p>21 MR. FARIES: Objection to form.</p> <p>22 THE WITNESS: They are good scientists. I</p> <p>23 do not question their qualifications.</p> <p>24 BY MR. HEGARTY:</p> <p>25 Q. Have you reviewed what the NCI editorial</p>	<p>1 A. Yes, it does.</p> <p>2 Q. If you turn over to page 15 of 21, that's</p> <p>3 reported at the top right-hand corner where it lists</p> <p>4 pages. I'm sorry, it's 14 of 21.</p> <p>5 Do you see the heading Perineal Talc</p> <p>6 Exposure under the larger heading of Factors With</p> <p>7 Inadequate Evidence of an Association, Risk of Ovarian</p> <p>8 Fallopian Tube and Primary Perineal Cancer?</p> <p>9 A. Yes, I do see that.</p> <p>10 Q. Have you read the paragraph below the</p> <p>11 heading Perineal Talc Exposure before right now?</p> <p>12 A. Yes, I have.</p> <p>13 Q. And as I just mentioned, that paragraph</p> <p>14 leads with a statement, The weight of evidence does</p> <p>15 not support an association between perineal talc</p> <p>16 exposure and an increased risk of ovarian cancer,</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. Do you disagree with that statement?</p> <p>20 A. My opinion differs from that statement,</p> <p>21 yes.</p> <p>22 Q. In fact, your opinion is just -- is</p> <p>23 completely opposite of that statement, correct?</p> <p>24 MR. FARIES: Objection to form.</p> <p>25 THE WITNESS: I think that this statement</p>

25 (Pages 94 to 97)

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<p>1 does not say the evidence says there is no 2 association. 3 BY MR. HEGARTY: 4 Q. Well, is it your opinion that the weight 5 of evidence does support an association between 6 perineal talc exposure and an increased risk of 7 ovarian cancer? 8 A. Yes, that is my opinion. 9 Q. And that statement is completely opposite 10 of their statement, correct? 11 A. Yes. 12 Q. And do you contend that the editorial 13 board members, which you know, didn't do a proper 14 review in preparing this summary that we just 15 reviewed? 16 MR. FARIES: Objection to form. 17 THE WITNESS: I am not making that 18 contention, no. 19 BY MR. HEGARTY: 20 Q. Are you critical of their evaluation that 21 has led to the publication of this statement? 22 MR. FARIES: Objection to form. 23 THE WITNESS: I think that it is possible 24 for reputable scientists to look at the evidence 25 and come to different conclusions based on how</p>	<p>1 A. I don't recall -- 2 MR. FARIES: Objection to form. 3 THE WITNESS: -- on a specific date when I 4 became aware of it. I just don't recall. 5 BY MR. HEGARTY: 6 Q. Do you agree that IARC conducted a full 7 and complete review of the question of whether talcum 8 powder products can be causally linked to ovarian 9 cancer back in 2006? 10 MR. FARIES: Objection to form. 11 THE WITNESS: Please say that one more 12 time. 13 BY MR. HEGARTY: 14 Q. Sure. Do you agree that IARC did a full 15 and complete review of the medical literature at the 16 time when it did its review of the issue of -- review 17 of looking at the issue of whether talcum powder 18 products can cause ovarian cancer? 19 MR. FARIES: Objection to form. 20 THE WITNESS: I think that IARC did a 21 thorough review. 22 BY MR. HEGARTY: 23 Q. Did they review all of the relevant 24 literature through 2006 as part of that review? 25 MR. FARIES: Objection to form.</p>
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<p>1 they evaluate and weight the evidence. I think 2 that that is not unreasonable that there may be 3 differences of opinion. 4 BY MR. HEGARTY: 5 Q. You then agree that this statement is not 6 an unreasonable statement to make, correct? 7 MR. FARIES: Objection to form. 8 THE WITNESS: I'm saying that it is 9 possible for other scientists to come to a 10 different conclusion based on the same review of 11 evidence. 12 BY MR. HEGARTY: 13 Q. Have you reviewed IARC's review of the 14 issue of talcum powder products and their possible 15 link to ovarian cancer? 16 A. Yes, I have. 17 Q. When did you first review IARC's review of 18 the issue of talcum powder products in ovarian cancer? 19 A. I don't recall specifically. 20 Q. Did you review it when it was published 21 back in 2010? 22 A. I don't remember the first time that I've 23 looked at it. 24 Q. Do you recall being aware of what IARC 25 concluded back in 2006 when it did its review?</p>	<p>1 THE WITNESS: To my knowledge, they did. 2 BY MR. HEGARTY: 3 Q. And based on their review, IARC concluded 4 that talcum powder products were possibly 5 carcinogenic, correct, class -- Category 2B? 6 MR. FARIES: Objection to form. 7 THE WITNESS: That is my recollection of 8 their conclusion, yes. 9 BY MR. HEGARTY: 10 Q. IARC did not conclude that talcum powder 11 products are carcinogenic, correct? 12 MR. FARIES: Objection to form. 13 THE WITNESS: They -- as you stated 14 before, their conclusion was that it was a 15 possible carcinogen. 16 BY MR. HEGARTY: 17 Q. Is that Group 2B? 18 A. I believe that's a categorization, yes. 19 Q. There are two higher groups that IARC can 20 place a substance into, correct? 21 A. That is correct. 22 Q. One is carcinogenetic, correct? 23 A. I -- yes. 24 Q. The other is probably carcinogenetic, 25 correct, or possible -- or probable carcinogen?</p>

26 (Pages 98 to 101)

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<p>1 A. Yes.</p> <p>2 Q. And IARC did not put talcum powder</p> <p>3 products in either of those two categories, correct?</p> <p>4 A. Right. As you stated, they described it</p> <p>5 as a possible carcinogen.</p> <p>6 Q. Even that decision was not unanimous,</p> <p>7 correct?</p> <p>8 MR. FARIES: Objection to form.</p> <p>9 THE WITNESS: I don't recall specifically</p> <p>10 how that was described.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. Was it -- do you have a -- do you know one</p> <p>13 way or another whether the decisions to place talc in</p> <p>14 the category of 2B was a unanimous decision?</p> <p>15 A. I just answered that. I don't know.</p> <p>16 Q. What is the phrase -- or strike that.</p> <p>17 Do you know what it means or the IARC</p> <p>18 designation of Category 2B means? Do you know that</p> <p>19 terminology?</p> <p>20 MR. FARIES: Objection to form.</p> <p>21 THE WITNESS: As you stated, it is a</p> <p>22 possible carcinogen, and I think that they have</p> <p>23 some criteria for putting a specific agent in a</p> <p>24 specific category.</p> <p>25</p>	<p>1 reviewed the IARC monograph as of the time you were</p> <p>2 first contacted by Plaintiffs' counsel about serving</p> <p>3 as an expert witness?</p> <p>4 A. It is very difficult to say specifically</p> <p>5 when I reviewed it. You know, it's just in generally</p> <p>6 trying to review literature, I don't -- I can't say</p> <p>7 did I -- when did I first recall -- review it, when</p> <p>8 did I last review it. It's just impossible for me to</p> <p>9 pinpoint that.</p> <p>10 Q. Do you recall IARC in its analysis saying</p> <p>11 that with regard to the epidemiologic and other</p> <p>12 literature, that the Working Group considered such</p> <p>13 evidence of a causal interpretation to be credible,</p> <p>14 but chance, bias, and confounding could not be ruled</p> <p>15 out with reasonable confidence? Do you recall them</p> <p>16 making that statement?</p> <p>17 MR. FARIES: Objection to form.</p> <p>18 THE WITNESS: I don't recall the specific</p> <p>19 wording. I recall something that -- some</p> <p>20 addressing of whether or not bias could come</p> <p>21 into play. I don't recall the exact wording.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. Do you recall IARC -- strike that.</p> <p>24 Did IARC find a dose response in the</p> <p>25 literature looking at talcum powder use and ovarian</p>
Page 103	Page 105
<p>1 BY MR. HEGARTY:</p> <p>2 Q. Do you know what that criteria is?</p> <p>3 A. Off the top of my head, I cannot describe</p> <p>4 it specifically.</p> <p>5 Q. Have you read IARC's 2010 monograph with</p> <p>6 regard to talcum powder products and ovarian cancer</p> <p>7 before being contacted by Plaintiffs' counsel?</p> <p>8 A. I believe that I have, but I don't -- I</p> <p>9 really don't recall the first time that I read it.</p> <p>10 Q. Do you recall if you agreed with IARC's</p> <p>11 findings at the time you reviewed the IARC monograph?</p> <p>12 MR. FARIES: Objection to form.</p> <p>13 THE WITNESS: I don't -- I don't really</p> <p>14 recall, you know, at that moment what my feeling</p> <p>15 was. Was it an agreement or disagreement, I</p> <p>16 just don't recall.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. Do you recall when it was you had last</p> <p>19 reviewed the IARC monograph as of the time you were</p> <p>20 contacted by Plaintiffs' counsel as potentially</p> <p>21 serving as an expert witness?</p> <p>22 A. I'm sorry.</p> <p>23 Q. Sure.</p> <p>24 A. I just didn't follow that question.</p> <p>25 Q. Do you recall when it was you last</p>	<p>1 cancer?</p> <p>2 MR. FARIES: Objection to form.</p> <p>3 THE WITNESS: I can't recall exactly how</p> <p>4 they analyzed it in relation to dose response.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q. Do you recall whether they looked at the</p> <p>7 translocation or transportation of talc from the</p> <p>8 perineum to the ovaries as part of their analysis?</p> <p>9 A. I believe they considered that, but,</p> <p>10 again, all the details of all the articles I've read</p> <p>11 are sometimes a little bit challenging to recall what</p> <p>12 was in what article.</p> <p>13 Q. IARC also looked at whether inhaled talc</p> <p>14 was a carcinogen. Are you aware of that?</p> <p>15 MR. FARIES: Objection to form.</p> <p>16 THE WITNESS: I don't recall reading that.</p> <p>17 (EXHIBIT NUMBER 7 WAS MARKED FOR IDENTIFICATION)</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. Let me mark as Exhibit Number 7 the IARC</p> <p>20 monograph, Volume 93, and I only brought one copy</p> <p>21 because it was too big --</p> <p>22 MR. FARIES: Yeah, I understand.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. -- to bring so you all have to share it.</p> <p>25 MR. FARIES: I assume you're going to turn</p>

27 (Pages 102 to 105)

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<p style="text-align: right;">Page 106</p> <p>1 to a page. I will take the --</p> <p>2 MR. HEGARTY: Yes.</p> <p>3 MR. KLATT: I'm sorry, that was which</p> <p>4 exhibit?</p> <p>5 MR. FARIES: Exhibit 7.</p> <p>6 MR. HEGARTY: This is 7.</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q. I asked you a moment ago about the</p> <p>9 statement of whether IARC was able to rule out chance,</p> <p>10 bias, or confounding with reasonable confidence. Do</p> <p>11 you recall me asking that question?</p> <p>12 A. Yes, I do.</p> <p>13 Q. Do you recall if you agreed at the time</p> <p>14 with IARC that chance, bias, and confounding could not</p> <p>15 be ruled out with reasonable confidence?</p> <p>16 MR. FARIES: Objection to form.</p> <p>17 THE WITNESS: As I have stated before, I</p> <p>18 do not recall exactly what my reaction was at</p> <p>19 the time that I read this.</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q. Let's go back to my question with regard</p> <p>22 to inhaled talc. If you would look at page 412, under</p> <p>23 the Section 6.3, Overall Evaluation.</p> <p>24 MR. FARIES: Hang on before you get --</p> <p>25 okay. I need to orient myself on what section</p>	<p style="text-align: right;">Page 108</p> <p>1 405. Okay. Okay, we've got it.</p> <p>2 MR. HEGARTY: Okay.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. If you would look at page 412. The</p> <p>5 section that reads 6.3, Overall Evaluation, first</p> <p>6 begins by stating that Perineal use of talc-based body</p> <p>7 powder is possibly carcinogenic to humans, Group 2B,</p> <p>8 correct?</p> <p>9 A. That's what it says, yes.</p> <p>10 Q. Do you agree that's where -- that is the</p> <p>11 group that IARC classified its talc assessment for</p> <p>12 purposes of this monograph?</p> <p>13 A. Yes.</p> <p>14 Q. The next line below that says: (Reading)</p> <p>15 Inhaled talc not containing</p> <p>16 asbestos or asbestiform fibers is not</p> <p>17 classifiable as to its</p> <p>18 carcinogenicity, Group 3.</p> <p>19 Do you see that?</p> <p>20 A. Yes, I do see that.</p> <p>21 Q. Do you agree with that statement?</p> <p>22 MR. FARIES: Objection to form.</p> <p>23 THE WITNESS: I agree that that is the</p> <p>24 conclusion that IARC made.</p> <p>25</p>
<p style="text-align: right;">Page 107</p> <p>1 we're in.</p> <p>2 MR. HEGARTY: Sure.</p> <p>3 MR. FARIES: And are we talking talc</p> <p>4 products or other kinds of talc?</p> <p>5 MR. HEGARTY: Feel free to look at the</p> <p>6 whole document --</p> <p>7 MR. FARIES: Yeah.</p> <p>8 MR. HEGARTY: -- if you want to.</p> <p>9 MR. FARIES: I'll keep it short here.</p> <p>10 MR. HEGARTY: Just try to keep the pages</p> <p>11 in order.</p> <p>12 MR. FARIES: I'll try. Okay, hang on.</p> <p>13 I'm keeping them in order.</p> <p>14 Did you by chance put a tab at the</p> <p>15 beginning of talc?</p> <p>16 MR. HEGARTY: I did not.</p> <p>17 MR. FARIES: Okay. Okay, okay. And --</p> <p>18 okay. Twelve. Ooh, I shouldn't have done that.</p> <p>19 Okay. So I just want to clarify for the</p> <p>20 record that you're asking her questions about</p> <p>21 the IARC's monograph, 93, regarding talc not</p> <p>22 containing asbestiform fibers?</p> <p>23 MR. HEGARTY: Correct.</p> <p>24 MR. FARIES: Okay. So there's that. And</p> <p>25 then if you need to refer to the -- let's see,</p>	<p style="text-align: right;">Page 109</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. Do you agree with their conclusion?</p> <p>3 MR. FARIES: Objection to form.</p> <p>4 THE WITNESS: In my -- my area of</p> <p>5 expertise is in epidemiologic studies, and I</p> <p>6 have not specifically identified studies that</p> <p>7 looked just at inhaled talc.</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q. So you have not done an analysis so you</p> <p>10 could comment on the Category 3 finding by IARC; is</p> <p>11 that correct?</p> <p>12 MR. FARIES: Objection to form.</p> <p>13 THE WITNESS: I have not done that</p> <p>14 analysis.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q. Do you agree with IARC's finding of</p> <p>17 talc-based body powders as possibly carcinogenetic to</p> <p>18 humans Group 2B?</p> <p>19 MR. FARIES: Objection to form.</p> <p>20 THE WITNESS: My opinion as I have</p> <p>21 expressed to you is stronger than this</p> <p>22 conclusion here.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. Was it stronger than the conclusion back</p> <p>25 when this was published in 2010?</p>

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<p>1 A. Once again, I do -- cannot recall exactly 2 what my opinion was at that time point. My opinion 3 has -- as more evidence arises, that has informed my 4 opinion. 5 Q. Well, are you able to pinpoint in any way 6 when you came to the opinion that talcum powder 7 products increased the risk of ovarian cancer, for 8 example, in the 2000s, between 2000 and 2010, if 9 somebody had asked you what your opinion was, would 10 you have said that my opinion is that talcum powder 11 products increase the risk of ovarian cancer? 12 MR. FARIES: Objection to form. This has 13 honestly been asked and answered several times. 14 You're welcome to repeat your answer, and then 15 maybe we can move on. 16 THE WITNESS: Right. I can't identify any 17 specific point where I formed this opinion. The 18 medical -- the epidemiologic literature has 19 evolved on it, has continued to accumulate, and 20 my opinion has always been informed by the body 21 of literature, the entire body of literature. 22 BY MR. HEGARTY: 23 Q. Well, would it be a fair statement, then, 24 that your opinion has been evolving on this issue over 25 time?</p>	<p>1 You did do -- you have been involved in studies 2 looking at talcum powder products and the risk of 3 ovarian cancer, correct? 4 A. Yes. 5 Q. You have been an author on several papers 6 that have reported relative risks or odds ratios in 7 looking at ovarian cancer risk with talcum powder 8 product -- with body powder product or talcum powder 9 product use, correct? 10 A. That is correct. 11 Q. And my question was, at the time you were 12 involved in the very first study that you did, do you 13 agree that you had not concluded that talcum powder 14 products cause ovarian cancer? 15 MR. FARIES: Objection to form. 16 THE WITNESS: When we do our studies and 17 develop our questionnaires, we are asking 18 questions about what we often say established 19 and hypothesized risk factors for the disease, 20 and there is a spectrum of evidence. And it's 21 hard to say, again, at the time that we started 22 these studies whether we had concluded that it 23 was a cause or that there was reason to study it 24 as a cause of ovarian cancer because of the body 25 of literature on it.</p>
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<p>1 MR. FARIES: Objection to form. 2 THE WITNESS: Yes, yes. 3 BY MR. HEGARTY: 4 Q. In particular, you didn't start out when 5 you looked at the very first study on talcum powder 6 products in ovarian cancer with the belief that talcum 7 powder products cause ovarian cancer, correct? 8 MR. FARIES: Objection to form. 9 THE WITNESS: Okay. I did not do the 10 first study of ovarian cancer and talc, okay? I 11 have been aware of epidemiologic studies 12 examining talc products in relation to ovarian 13 cancer for quite some time. One would never 14 make a conclusion about causality based on a 15 single epidemiologic study, and so the first 16 time you see something like that, it is very 17 reasonable to say, hum, that's interesting, but 18 only with additional studies would one make a 19 conclusion. And so as studies have been done -- 20 as we all know, there have been several, 21 probably a couple dozen or more epidemiologic 22 studies, and so as those studies have come out, 23 of course my opinion has evolved. 24 BY MR. HEGARTY: 25 Q. My question was a little bit different.</p>	<p>1 BY MR. HEGARTY: 2 Q. With regard to the studies that you've 3 been involved in in which you've reported on the 4 results of women using talcum powder products and the 5 risk of ovarian cancer, is that data, the 6 questionnaires, the data, the work product, the study 7 notes, is all that material still in existence? 8 MR. FARIES: Objection to form. 9 THE WITNESS: The two studies that I have 10 been involved in that have been -- have done 11 data collection on talc have been the North 12 Carolina Ovarian Cancer Study and then the 13 African-American Cancer Epidemiology Study, and 14 those data are -- yes, still exist, the 15 questionnaires still exist. 16 BY MR. HEGARTY: 17 Q. How about all of the work generated in 18 ultimately bringing that data to publication, drafts, 19 notes, e-mails, exchanges back and forth, is all that 20 data still in existence? 21 MR. FARIES: Objection to form. 22 THE WITNESS: I -- again, you're 23 expressing this in an absolute. All of it, I 24 would say probably not. You know, it's not 25 typical to save every draft and -- you know, and</p>

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<p style="text-align: right;">Page 114</p> <p>1 again, like for example this study (indicating), 2 Joellen Schildkraut was the lead author, and so 3 I cannot speak to whether she has retained every 4 draft or not. 5 BY MR. HEGARTY: 6 Q. How about you, do you have copies or do 7 you have data, materials still remaining from the 8 studies that you have been involved in looking at 9 talcum powder product or body powder product use in 10 ovarian cancer? Do you have your -- 11 MR. FARIES: Objection. 12 BY MR. HEGARTY: 13 Q. Do you have materials still in your 14 possession at your office or your home? 15 A. So "materials" as defined by? 16 Q. Anything dealing with those studies? 17 A. By IRB, Institutional Review Board, 18 regulations, the data are retained for a minimum of 19 six years after the studies are completed. 20 Q. How about any other work product you 21 generated in working on those studies? Do you still 22 have any of that work product still in your 23 possession? 24 A. The work product, again, as you said, like 25 drafts and --</p>	<p style="text-align: right;">Page 116</p> <p>1 group, entity or organization who has the same opinion 2 you have with regard to the use of talcum powder 3 products and ovarian cancer whether it's risk or 4 cause? 5 MR. FARIES: Objection to form. 6 THE WITNESS: I can't recall. I can't -- 7 I don't know of one. 8 BY MR. HEGARTY: 9 Q. Have you ever made the statement in any 10 publication you have ever written that talcum powder 11 products increase the risk of ovarian cancer? 12 MR. FARIES: Objection to form. 13 THE WITNESS: I am -- I can't recall if I 14 have made specifically that statement. And, 15 again, it is important to bear in mind that I 16 have often worked as part of a group of 17 investigators, and so, for example, this paper 18 was not a paper that I wrote, that it was 19 Dr. Schildkraut that wrote it. And I think that 20 like, for example, statements like "our results 21 support that body powder is a modifiable risk 22 factor for EOC," so epithelial ovarian cancer, 23 "among African-American women." I think it 24 is -- this -- the gist of the statement they 25 use.</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. Notes, notebooks, any memorandum, if any 2 exist, do you have any of that material still in your 3 possession? 4 A. I don't believe that there were any 5 notebooks or notes in regard to that. 6 Q. If there were any such, would you still 7 have possession of those? 8 A. I don't think they exist, I just -- I just 9 don't. 10 Q. Can you cite for me any medical or 11 scientific group, entity, or organization who has said 12 that the use of talcum powder products causes ovarian 13 cancer? 14 MR. FARIES: Objection to form. 15 THE WITNESS: Okay. I do not recall any 16 group that has used specifically that 17 terminology. I think that IARC has described it 18 as possibly carcinogenic. 19 BY MR. HEGARTY: 20 Q. Can you cite any medical or scientific 21 group, entity or organization who has said that talcum 22 powder products increase the risk of ovarian cancer? 23 A. I can't think of any off the top of my 24 head. 25 Q. Can you identify any medical or scientific</p>	<p style="text-align: right;">Page 117</p> <p>1 BY MR. HEGARTY: 2 Q. Well, my question was very specific. Have 3 you ever made the statement in any publication which 4 you were an author on or with any public -- any other 5 document you have authored that use of body powders, 6 talc-based body powders, cause ovarian cancer? 7 MR. FARIES: Objection to form. 8 THE WITNESS: I don't think I have written 9 that in a published document. 10 BY MR. HEGARTY: 11 Q. Have you written in any published document 12 in which you are listed as an author or were an author 13 that talc body powders increase the risk of ovarian 14 cancer? 15 MR. FARIES: Objection to form. 16 BY MR. HEGARTY: 17 Q. Versus those women who do not use them? 18 MR. FARIES: Same objection. 19 THE WITNESS: I can't remember the exact 20 phrasing being used like that. 21 BY MR. HEGARTY: 22 Q. Can you cite for me any author who has 23 ever written in any publication that talcum powder 24 products cause ovarian cancer? 25 MR. FARIES: Objection to form.</p>

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<p>1 THE WITNESS: I can't recall any -- any</p> <p>2 document that has that exact phrasing.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. Can you cite for me any author in any</p> <p>5 publication who has ever stated that use of talcum</p> <p>6 powder products increase the risk of ovarian cancer?</p> <p>7 A. I'm just having trouble recalling any</p> <p>8 specific wording like that.</p> <p>9 Q. Can you identify for me any doctor who</p> <p>10 treats ovarian cancer who has the same opinions you do</p> <p>11 about cause?</p> <p>12 MR. FARIES: Objection to form.</p> <p>13 THE WITNESS: I actually have not</p> <p>14 discussed that with -- that specific question</p> <p>15 with any gynecologic oncologist.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. Have you discussed with any gynecologic</p> <p>18 oncologist your opinion that talcum powder products</p> <p>19 increase the risk of ovarian cancer?</p> <p>20 A. I have not had a specific discussion in</p> <p>21 that regard, no.</p> <p>22 Q. You provided to us the primary opinion in</p> <p>23 this case that women who use talcum powder products</p> <p>24 are at a higher risk of ovarian cancer than women who</p> <p>25 did not use them. Do you recall making that</p>	<p>1 products are at a higher risk of ovarian cancer than</p> <p>2 women who did not use them?</p> <p>3 A. That is correct.</p> <p>4 Q. And before you were contacted by</p> <p>5 Mr. Gibson or Ms. Parfitt, I take it from your last</p> <p>6 answer, that you had not come -- yet come to the</p> <p>7 opinion that talcum powder products cause ovarian</p> <p>8 cancer, correct?</p> <p>9 MR. FARIES: Objection to form.</p> <p>10 THE WITNESS: I -- epidemiologists by</p> <p>11 nature tend to be very cautious. And it was,</p> <p>12 you know, reviewing all of the literature in</p> <p>13 probably more detail than I had ever reviewed it</p> <p>14 before led me to come to the conclusion that I</p> <p>15 think that the evidence is strong enough to say</p> <p>16 with a reasonable degree of scientific certainty</p> <p>17 that talc use can cause ovarian cancer.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. Have you ever used, before being contacted</p> <p>20 by Plaintiffs' counsel in this case, the phrase</p> <p>21 "reasonable degree of scientific certainty"?</p> <p>22 A. I don't think that I have.</p> <p>23 Q. What does that phrase mean to you?</p> <p>24 A. I take it to mean that when considering</p> <p>25 the bulk -- the overall evidence, that it is</p>
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<p>1 statement?</p> <p>2 A. I do.</p> <p>3 Q. Did you have that opinion before being</p> <p>4 contacted by Plaintiffs' counsel in this case?</p> <p>5 A. I had the opinion that women who use body</p> <p>6 powder are at increased risk for ovarian cancer for,</p> <p>7 yes, before I was contacted by the Plaintiffs'</p> <p>8 attorneys.</p> <p>9 Q. You also provided the opinion that women</p> <p>10 who use that -- strike that.</p> <p>11 You also provided the opinion that talcum</p> <p>12 powder products cause ovarian cancer. Do you recall</p> <p>13 making -- telling us that today?</p> <p>14 A. I do.</p> <p>15 Q. Did you have that opinion before being</p> <p>16 contacted by Plaintiffs' counsel in this case?</p> <p>17 A. My opinion, I think that it became</p> <p>18 stronger as I reviewed the body of literature in -- in</p> <p>19 relation to this. It was -- I held the opinion that</p> <p>20 it was a risk factor. It became stronger as I really</p> <p>21 delved into it in greater detail.</p> <p>22 Q. And let me make sure I'm clear on</p> <p>23 Plaintiffs' counsel. Before being contacted by</p> <p>24 Mr. Gibson or Ms. Parfitt is it your testimony that it</p> <p>25 was your opinion that women who used talcum powder</p>	<p>1 reasonable to make that statement. I think that it</p> <p>2 takes -- it takes into account that science evolves</p> <p>3 and there may be additional data that could arise</p> <p>4 and -- in which the opinion may evolve, but based on</p> <p>5 the body of evidence now I do feel that there is</p> <p>6 reasonable scientific certainty.</p> <p>7 Q. With regard to your prior testimony as to</p> <p>8 looking at cause versus increased risk, you mentioned</p> <p>9 that that opinion came after you had done an in-depth</p> <p>10 review, correct?</p> <p>11 A. That is correct.</p> <p>12 Q. So it would be a fair statement to say</p> <p>13 before you were contacted by either Mr. Gibson or</p> <p>14 Ms. Parfitt that you had not done an in-depth review</p> <p>15 of all of the literature concerning talcum powder</p> <p>16 products and ovarian cancer, correct?</p> <p>17 MR. FARIES: Objection to form.</p> <p>18 THE WITNESS: I think that it is a matter</p> <p>19 of degree. I think that I was aware of the</p> <p>20 epidemiologic studies that had addressed this.</p> <p>21 And as I was -- after I was contacted about this</p> <p>22 case, I tried to do a very critical, very</p> <p>23 in-depth reviews.</p> <p>24 BY MR. HEGARTY:</p> <p>25 Q. A review you had not yet done before being</p>

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<p style="text-align: right;">Page 122</p> <p>1 contacted by Ms. Parfitt and/or Mr. Gibson, correct?</p> <p>2 MR. FARIES: Objection to form.</p> <p>3 THE WITNESS: As I said, I think that it</p> <p>4 is not a matter of had I not or had I done it, I</p> <p>5 think that it was, perhaps, the level of detail.</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q. You did a more detailed review and</p> <p>8 analysis after being contacted by Ms. Parfitt and/or</p> <p>9 Mr. Gibson than you had done before they had contacted</p> <p>10 you, correct?</p> <p>11 MR. FARIES: Objection to form.</p> <p>12 THE WITNESS: Correct.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q. Have you ever provided the opinions you've</p> <p>15 given us here today to any doctor who has ever treated</p> <p>16 a patient for ovarian cancer?</p> <p>17 A. I have not.</p> <p>18 Q. That includes any doctor at Duke, correct?</p> <p>19 A. That is correct.</p> <p>20 Q. You've not told your opinions about talc</p> <p>21 and ovarian cancer to any doctor in your own medical</p> <p>22 school, correct?</p> <p>23 MR. FARIES: Objection to form, asked and</p> <p>24 answered.</p> <p>25 THE WITNESS: That is correct.</p>	<p style="text-align: right;">Page 124</p> <p>1 MR. FARIES: Objection to form.</p> <p>2 THE WITNESS: The only discussion that I</p> <p>3 had about my involvement in this was with an</p> <p>4 author. It was a former student, and she had</p> <p>5 been contacted by an attorney and asked me what</p> <p>6 I thought about it and if I had had any</p> <p>7 involvement. And I had just mentioned to her</p> <p>8 that I was working with the Plaintiffs'</p> <p>9 attorney. But I have not discussed otherwise.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q. Who was that person?</p> <p>12 A. Who was the person?</p> <p>13 Q. Yes.</p> <p>14 A. Her name is Rachel Weber.</p> <p>15 Q. When did this discussion happen?</p> <p>16 A. I believe it was in the fall of last year.</p> <p>17 Q. Would it be a fair statement that with</p> <p>18 regard to the opinions you've offered in this case,</p> <p>19 that you've held those opinions for at least a year?</p> <p>20 MR. FARIES: Objection to form.</p> <p>21 THE WITNESS: Yes, that is a fair</p> <p>22 statement.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. Sitting here today you're not testifying</p> <p>25 on behalf of Duke University, correct?</p>
<p style="text-align: right;">Page 123</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. Do you know any of the gynecologic</p> <p>3 oncologists at Duke?</p> <p>4 A. Yes, I do.</p> <p>5 Q. Can you name for me the ones you know?</p> <p>6 A. I know Dr. Andrew Berchuck, Dr. Laura</p> <p>7 Havrilesky. I have met Angeles Alvarez Secord. I</p> <p>8 believe those are the ones that I know.</p> <p>9 Q. You've not spoken to them about your</p> <p>10 opinions that you provided here today, correct?</p> <p>11 A. I have not had a direct conversation with</p> <p>12 them.</p> <p>13 Q. Well, have you had any conversation with</p> <p>14 them about your opinions in this case?</p> <p>15 A. No, I have not.</p> <p>16 Q. Have you told any of the authors that</p> <p>17 you're on in the Schildkraut paper of your opinions in</p> <p>18 this case?</p> <p>19 MR. FARIES: Objection to form.</p> <p>20 THE WITNESS: No, I have not discussed my</p> <p>21 involvement in this case with any of the</p> <p>22 authors.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. How about any of the authors on any of the</p> <p>25 papers you've been on?</p>	<p style="text-align: right;">Page 125</p> <p>1 A. No, I am not.</p> <p>2 Q. You're not coming here today testifying</p> <p>3 that Duke University or the Duke Medical School has</p> <p>4 the same opinions that you do, correct?</p> <p>5 MR. FARIES: Objection to form.</p> <p>6 THE WITNESS: No, I am not.</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q. You're here on your own behalf, right?</p> <p>9 A. That is correct.</p> <p>10 Q. And the opinions you hold are your own</p> <p>11 opinions, right?</p> <p>12 A. That is correct.</p> <p>13 Q. Can you identify for me any regulatory</p> <p>14 body who has required a warning concerning genital</p> <p>15 talc use and ovarian cancer?</p> <p>16 MR. FARIES: Objection to form.</p> <p>17 THE WITNESS: No, I cannot.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. How about any regulatory body who has</p> <p>20 concluded that genital talcum powder use is a risk</p> <p>21 factor or a cause of ovarian cancer?</p> <p>22 MR. FARIES: Objection to form.</p> <p>23 THE WITNESS: No, I cannot.</p> <p>24 BY MR. HEGARTY:</p> <p>25 Q. Outside of your work with Plaintiffs'</p>

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<p>1 counsel, has anyone before being contacted by</p> <p>2 Plaintiffs' counsel sought out your opinions regarding</p> <p>3 talc and ovarian cancer?</p> <p>4 A. Before Plaintiffs' counsel --</p> <p>5 Q. Yes.</p> <p>6 A. -- contacted me, has anybody else sought</p> <p>7 out my opinion?</p> <p>8 Q. Correct.</p> <p>9 A. No.</p> <p>10 Q. Before being contacted by Plaintiffs'</p> <p>11 counsel, has anybody sought out your opinion on</p> <p>12 whether talcum powder products increase the risk of</p> <p>13 ovarian cancer?</p> <p>14 A. No.</p> <p>15 Q. Or about potential causes of ovarian</p> <p>16 cancer, generally? Has anybody -- strike that.</p> <p>17 Has anybody sought out your opinions,</p> <p>18 generally, about the causes of ovarian cancer?</p> <p>19 A. I'm not sure exactly how to interpret that</p> <p>20 question. I have -- you know, I have done things over</p> <p>21 the course of my career such as reviewing grant</p> <p>22 applications, several years ago participated in a CDC</p> <p>23 panel about ovarian cancer. And so those I think that</p> <p>24 it would be fair to characterize them as people</p> <p>25 seeking my opinion about -- my -- my opinion, my</p>	<p>1 specifically a cancer epidemiology course.</p> <p>2 Q. Have you ever provided to any of your</p> <p>3 peers in any lecture format or otherwise the opinions</p> <p>4 you've offered here today?</p> <p>5 A. No, I have not.</p> <p>6 Q. Do you consider yourself an expert in the</p> <p>7 possible association between asbestos -- strike that.</p> <p>8 Do you consider yourself to be an expert</p> <p>9 in asbestos-causing ovarian cancer?</p> <p>10 MR. FARIES: Objection to form.</p> <p>11 THE WITNESS: I consider myself to be an</p> <p>12 expert in the epidemiology of ovarian cancer. I</p> <p>13 do not consider myself to be, specifically, an</p> <p>14 expert about asbestos.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q. Have you conducted any original research</p> <p>17 on asbestos in talcum powder products and ovarian</p> <p>18 cancer?</p> <p>19 MR. FARIES: Objection to form.</p> <p>20 THE WITNESS: Please state that again.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q. Sure. Have you conducted any original</p> <p>23 research looking at the potential for asbestos to be</p> <p>24 in talcum powder products?</p> <p>25 A. I think this goes back to the questions</p>
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<p>1 knowledge about ovarian cancer.</p> <p>2 Q. I'd asked you previously about your</p> <p>3 opinions before being contacted by Plaintiffs' counsel</p> <p>4 through the present date. Have you provided the</p> <p>5 opinions you've given us here today to any group,</p> <p>6 person or entity outside of this litigation?</p> <p>7 MR. FARIES: Objection to form.</p> <p>8 THE WITNESS: No, I have not.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q. Has NCI ever sought out your opinions with</p> <p>11 regard to talcum powder products and ovarian cancer?</p> <p>12 A. No, they have not.</p> <p>13 Q. How about any scientific or medical body</p> <p>14 or organization?</p> <p>15 A. No, they have not.</p> <p>16 Q. Do you teach courses?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Is that currently?</p> <p>19 A. Yes.</p> <p>20 Q. Have you ever taught to any of your</p> <p>21 opinions -- have you ever taught to any of the</p> <p>22 students in your classes the opinions you've provided</p> <p>23 to us here today?</p> <p>24 A. No, I do not teach -- the course that I</p> <p>25 teach is called, Evidence-based Medicine. It is not</p>	<p>1 that you've asked earlier. As you clearly know, we</p> <p>2 did do a study that was evaluating talcum powder in</p> <p>3 relation to ovarian cancer, and so talcum powder with</p> <p>4 all its constituents. We would not be able to</p> <p>5 distinguish between asbestos-containing and</p> <p>6 nonasbestos-containing talcum powder.</p> <p>7 Q. My question is a little bit different.</p> <p>8 You had commented earlier about reviewing studies or</p> <p>9 literature that has commented on the potential for</p> <p>10 asbestos to be in talcum powder products. Do you</p> <p>11 recall saying that earlier?</p> <p>12 A. That I looked at some of those studies.</p> <p>13 Q. Have you ever been involved in any study</p> <p>14 looking at whether talcum powder products actually had</p> <p>15 asbestos in them?</p> <p>16 MR. FARIES: Objection to form.</p> <p>17 THE WITNESS: Once again, that is outside</p> <p>18 of my realm of expertise. I do not do any</p> <p>19 mineral studies, testing, like that.</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q. Has there been any study looking at</p> <p>22 actually asbestos in talcum powder products and that</p> <p>23 link -- and such a link -- strike that. Let me say it</p> <p>24 again.</p> <p>25 Have there been, actually, any studies</p>

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<p>1 that have identified products, talcum powder products, 2 that actually have asbestos in them and looking at 3 those products link to ovarian cancer? 4 MR. FARIES: Objection to form. 5 THE WITNESS: I think that it goes back to 6 the same thing that I've said before. There is 7 no way to do studies of ovarian cancer and -- in 8 relation to talcum powder use to distinguish 9 between asbestos-containing or not. 10 BY MR. HEGARTY: 11 Q. You are not a medical doctor, correct? 12 A. That is correct. 13 Q. And you have never been involved in the 14 care and treatment of a patient with ovarian cancer, 15 correct? 16 A. No, I have not. 17 Q. You are not authorized to treat patients, 18 correct? 19 A. No, I am not. 20 Q. And you have never analyzed a patient's 21 risk factors for ovarian cancer, true? 22 A. No, I have not. 23 Q. You have never attempted to look at a 24 patient's risk factors and determine which factor, if 25 any, had anything to do with their ovarian cancer,</p>	<p>1 MR. FARIES: Objection to form. 2 THE WITNESS: I know several women who 3 have ovarian cancer. I have not spoken to them, 4 specifically, about their use of talcum powder. 5 But it is a quite ubiquitous exposure, so it is 6 very possible that they did have that exposure. 7 BY MR. HEGARTY: 8 Q. Is it correct that you don't intend, in 9 this case, to offer the opinion that any particular 10 woman's use of talcum powder products caused their 11 ovarian cancer? 12 A. I was asked to comment on the general 13 causation meaning it is pulling on my expertise as a 14 population scientist. I will not be commenting on any 15 specific woman. 16 Q. If we talk about statistical significance 17 and if we look at relative risk or odds ratios, in 18 that analysis one is considered the null value, 19 correct? 20 A. That is correct. 21 Q. And null value would indicate no 22 association between the exposure you're looking at and 23 the disease you're looking at, correct? 24 A. Yes. 25 Q. If a study is statistically significant,</p>
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<p>1 correct? 2 A. No. 3 Q. Are you aware of a method published in the 4 medical literature for reliably determining the cause 5 of an individual patient's ovarian cancer? 6 MR. FARIES: Objection to form. 7 THE WITNESS: I'm not aware of anything 8 like that. 9 BY MR. HEGARTY: 10 Q. Do you know the names of the plaintiffs in 11 this case? 12 MR. FARIES: Objection to form. 13 THE WITNESS: No, I do not. 14 BY MR. HEGARTY: 15 Q. Do you know how many plaintiffs are in 16 this case? 17 A. No, I do not. 18 Q. Do you know anything about them, where 19 they live, where they grew up, their asbestos -- their 20 asbestos exposures, their talcum powder product 21 exposure? Do you know any of that information? 22 A. No, I do not. 23 Q. Do you have any personal knowledge of any 24 patient who has used talcum powder products and 25 developed ovarian cancer?</p>	<p>1 it means that the likelihood of the result is caused 2 by something other than random chance, correct? 3 MR. FARIES: Objection to form. 4 THE WITNESS: The statistical significance 5 is one tool that we use to evaluate the results 6 from a study. 7 BY MR. HEGARTY: 8 Q. Let me ask it a different way. 9 A. Okay. 10 Q. If a study is not statistically 11 significant, it means the result could be due to 12 random chance, correct? 13 MR. FARIES: Objection to form. 14 THE WITNESS: Okay. It is -- if it is not 15 statistically significant that -- and you 16 give -- a 95 percent confidence interval is 17 reported, that is indicating that if you had 18 taken another sample from the population, this 19 is a plausible range of values that would be 20 statistically possible if you were able to 21 repeat the study. 22 BY MR. HEGARTY: 23 Q. And a confidence interval includes the 24 value of one to a 95 percent -- a 95 percent 25 confidence interval would mean that the result could</p>

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<p style="text-align: right;">Page 134</p> <p>1 be just due to chance, correct?</p> <p>2 MR. FARIES: Objection to form.</p> <p>3 THE WITNESS: It -- yes, that is how one</p> <p>4 could interpret that.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q. Another way to look at it is the null</p> <p>7 value could be the actual value, correct?</p> <p>8 A. It could be the actual value. The actual</p> <p>9 value could be higher than the reported relative risk,</p> <p>10 the confidence interval.</p> <p>11 Q. But it also could be lower too, correct?</p> <p>12 A. That is correct.</p> <p>13 Q. And when you get to both ends of the</p> <p>14 confidence interval, it's less likely it's at either</p> <p>15 end, correct?</p> <p>16 A. That's correct. The point estimate is</p> <p>17 the -- the best representation of the data from that</p> <p>18 study.</p> <p>19 Q. If you have a non-statistically</p> <p>20 significant finding, you cannot draw the conclusion in</p> <p>21 that study that the exposure is related to the</p> <p>22 condition study, correct?</p> <p>23 MR. FARIES: Objection to form.</p> <p>24 THE WITNESS: Okay. Again, I'd like to</p> <p>25 emphasize the point that one would never make a</p>	<p style="text-align: right;">Page 136</p> <p>1 A. One study.</p> <p>2 Q. If you find a non statistically</p> <p>3 significant result, then you cannot say that there's</p> <p>4 any association in that study between the exposure and</p> <p>5 the disease?</p> <p>6 MR. FARIES: Objection to form.</p> <p>7 THE WITNESS: It would be fair to say that</p> <p>8 there is not a statistically significant</p> <p>9 association.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q. Do you agree that epidemiology focuses on</p> <p>12 the question of general causation rather than that of</p> <p>13 specific causation?</p> <p>14 A. Could you, please, define those terms as</p> <p>15 you understand them?</p> <p>16 Q. Well, you indicated a moment ago that you</p> <p>17 were here to comment on general causation.</p> <p>18 A. Okay. I just want to make sure we're on</p> <p>19 the same page.</p> <p>20 Q. So you have an understanding of what</p> <p>21 general causation is, correct?</p> <p>22 MR. FARIES: Objection to form.</p> <p>23 THE WITNESS: I do have an understanding.</p> <p>24 I -- please, you know, tell me your</p> <p>25 understanding as well to make sure we're on the</p>
<p style="text-align: right;">Page 135</p> <p>1 conclusion like that from a single study. We --</p> <p>2 in epidemiology we would always rely on multiple</p> <p>3 studies to make our conclusions.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. My question's a little bit different. I</p> <p>6 think your comment about not drawing a conclusion from</p> <p>7 a single study would also include a study that does</p> <p>8 come out statistically significant, correct?</p> <p>9 A. That is correct.</p> <p>10 Q. But if you have a study that's not</p> <p>11 statistically significant where you're looking at an</p> <p>12 exposure and a disease, that would mean you can't draw</p> <p>13 the conclusion that the exposure is associated with</p> <p>14 the disease, correct?</p> <p>15 MR. FARIES: Objection to form.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. From that study?</p> <p>18 MR. FARIES: Same objection.</p> <p>19 THE WITNESS: Again, it is not</p> <p>20 statistically significant, but one would never</p> <p>21 make the conclusion on the basis of one study.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. And my question really focused on that --</p> <p>24 A. I'm sorry.</p> <p>25 Q. -- only that one study.</p>	<p style="text-align: right;">Page 137</p> <p>1 same page.</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q. Well, you also commented a moment ago that</p> <p>4 you're not here to testify about specific causation,</p> <p>5 correct?</p> <p>6 A. I said that I was not going to testify</p> <p>7 about any specific woman, I believe.</p> <p>8 Q. So using the definitions that you apply to</p> <p>9 general and specific causation, do you agree that</p> <p>10 epidemiology focuses on the question of general</p> <p>11 causation rather than that of specific causation?</p> <p>12 MR. FARIES: Objection to form.</p> <p>13 THE WITNESS: I think that, yes,</p> <p>14 epidemiology focuses on general causation in the</p> <p>15 studying populations, not individuals.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. Do you agree that there are, generally,</p> <p>18 three categories of phenomena that could result in an</p> <p>19 association finding in a study to be erroneous,</p> <p>20 chance, bias and confounding?</p> <p>21 MR. FARIES: Objection to form.</p> <p>22 THE WITNESS: Those -- yes, those are</p> <p>23 things we consider in all studies.</p> <p>24 BY MR. HEGARTY:</p> <p>25 Q. Well, each of those could result in a</p>

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<p style="text-align: right;">Page 138</p> <p>1 finding in a study to be erroneous correct?</p> <p>2 A. Correct.</p> <p>3 Q. The way to account for chance is through</p> <p>4 statistical significance, correct?</p> <p>5 MR. FARIES: Objection to form.</p> <p>6 THE WITNESS: Not exclusively.</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q. How else can you account for a statistical</p> <p>9 chance besides statistical significance?</p> <p>10 A. Okay. Once, again, considering the entire</p> <p>11 body of literature. A single study, that is not</p> <p>12 statistically significant, but it would say that</p> <p>13 they -- those findings are compatible with a chance</p> <p>14 finding. But when you consider the whole body of</p> <p>15 literature, there may be some studies that did not</p> <p>16 reach statistically significance that could play into</p> <p>17 the whole body of -- contribute to the whole body of</p> <p>18 literature.</p> <p>19 Q. Do you agree that within an individual</p> <p>20 study a finding of statistical significance does not</p> <p>21 rule out that the result was due to bias or</p> <p>22 confounding?</p> <p>23 MR. FARIES: Objection to form.</p> <p>24 THE WITNESS: I do agree with that.</p> <p>25</p>	<p style="text-align: right;">Page 140</p> <p>1 retrospective case-control study, correct?</p> <p>2 A. It is something that one would always</p> <p>3 think about in a case-control study.</p> <p>4 Q. Recall bias in a retrospective</p> <p>5 case-control study can distort an evaluation of</p> <p>6 whether the exposure is actually related to the</p> <p>7 disease, correct?</p> <p>8 MR. FARIES: Objection to form.</p> <p>9 THE WITNESS: Recall bias can lead to an</p> <p>10 erroneous conclusion, yes.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. Misclassification bias can also lead to an</p> <p>13 erroneous conclusion in a study, correct?</p> <p>14 MR. FARIES: Objection to form.</p> <p>15 THE WITNESS: It may, yes.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. And confounding is where there -- is where</p> <p>18 there could be another association in the study that</p> <p>19 confuses the relationship between what you're looking</p> <p>20 at and the disease, correct?</p> <p>21 A. That is correct.</p> <p>22 Q. In every study there exists the potential</p> <p>23 for unknown confounders, correct?</p> <p>24 MR. FARIES: Objection to form.</p> <p>25 THE WITNESS: That is possible, yes.</p>
<p style="text-align: right;">Page 139</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. Do you agree that in a case-control study,</p> <p>3 retrospective case-control study, there are a number</p> <p>4 of potential sources of bias?</p> <p>5 MR. FARIES: Objection to form.</p> <p>6 THE WITNESS: I agree with that, but I</p> <p>7 also think that that is true of any study</p> <p>8 design.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q. Okay. It's your belief that any study</p> <p>11 design whether it's randomized, placebo controlled,</p> <p>12 cohort, case-control, prospective study, has potential</p> <p>13 bias in it?</p> <p>14 MR. FARIES: Objection to form.</p> <p>15 THE WITNESS: I do agree that any study</p> <p>16 design can have some bias in it.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. One type of bias is recall bias, correct?</p> <p>19 A. That is correct.</p> <p>20 Q. And recall bias is where individuals with</p> <p>21 the disease, the cases, tend to recall past exposures</p> <p>22 more readily than individuals with no disease,</p> <p>23 correct?</p> <p>24 A. That is how the bias is typically defined.</p> <p>25 Q. Recall bias is a concern in every</p>	<p style="text-align: right;">Page 141</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. And when considering bias and confounders,</p> <p>3 the weaker the association, the lower the relative</p> <p>4 risk is or odds ratio, the greater the concern is that</p> <p>5 bias and confounding could be the result of that</p> <p>6 relative risk or odds ratio, correct?</p> <p>7 MR. FARIES: Objection to form.</p> <p>8 THE WITNESS: We consider confounding</p> <p>9 regardless of the strength of the association.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q. But do you -- I'm sorry, go ahead. I</p> <p>12 didn't mean to interrupt.</p> <p>13 A. Go ahead.</p> <p>14 Q. Do you agree, though, that there is</p> <p>15 greater concern about bias and confounding when you're</p> <p>16 dealing with a low relative risk or odds ratio versus</p> <p>17 a high relative risk or odds ratio like one that's 10,</p> <p>18 20 or 30?</p> <p>19 MR. FARIES: Objection to form.</p> <p>20 THE WITNESS: Okay. I -- in general terms</p> <p>21 yes. Yes.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. For example, if you're doing a study on</p> <p>24 smoking and lung cancer and you come up with a</p> <p>25 relative risk of ten, is it correct that you're less</p>

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<p style="text-align: right;">Page 142</p> <p>1 likely to be concerned about the potential effect on 2 that finding by confounders or biases? 3 MR. FARIES: Objection to form. 4 THE WITNESS: You would be concerned about 5 confounding regardless of the strength of the 6 association. If it is a relative risk that is 7 very large, it would have to be a factor that 8 was associated with both the exposure, in that 9 case the smoking, and the outcome to a similar 10 degree of strength. 11 MR. FARIES: Okay. Mark, can you find a 12 stopping point here -- 13 MR. HEGARTY: Yeah. 14 MR. FARIES: -- shortly? 15 MR. HEGARTY: Give me about -- just about 16 a few minutes -- 17 MR. FARIES: Okay. 18 MR. HEGARTY: -- and then I'll be done. A 19 few minutes here. 20 BY MR. HEGARTY: 21 Q. Do you agree that the size of an odds 22 ratio or relative risk is an important consideration 23 in evaluating the plausibility of a causal 24 relationship between the exposure and the disease? 25 MR. FARIES: Objection to form.</p>	<p style="text-align: right;">Page 144</p> <p>1 same thing? 2 A. In a general sense, yes. 3 Q. Do you agree that epidemiologic -- 4 epidemiology or epidemiologic evidence by itself is 5 insufficient to establish causality? 6 MR. FARIES: Objection to form. 7 THE WITNESS: When we -- again, in 8 epidemiology, we often rely on the Bradford Hill 9 criteria. And it's not just the epidemiologic 10 evidence, but a very important consideration is 11 the consideration of a plausible biological 12 mechanism. 13 BY MR. HEGARTY: 14 Q. And consideration of a plausible biologic 15 mechanism would take the analysis beyond just 16 epidemiologic studies, correct? 17 A. It would consider data from beyond the 18 epidemiologic study, yes. 19 Q. Do you agree that a risk factor is not 20 necessarily a causal factor? 21 MR. FARIES: Objection to form. 22 THE WITNESS: I -- I do agree that there 23 are examples of that, yes. 24 BY MR. HEGARTY: 25 Q. Have you ever been on a panel for a CDC?</p>
<p style="text-align: right;">Page 143</p> <p>1 THE WITNESS: One considers the size of 2 the odds ratio, but one would also bear in mind, 3 and it is pointed out in numerous papers, that 4 some associations may be smaller in magnitude 5 but still plausible and real. 6 BY MR. HEGARTY: 7 Q. When you say it's a consideration, what do 8 you mean? The size of the relative risk or odds ratio 9 is a consideration in assessing a causal relationship 10 between the exposure and the disease? 11 A. Okay. You know, as I have stated earlier, 12 the Bradford Hill viewpoints, I don't want to use word 13 "criteria" because he doesn't use that, but the 14 strength of the association is one of the 15 considerations that is described there. So it's -- it 16 is taken into account in the total picture. 17 Q. Do you agree that in looking at 18 epidemiologic studies the presence of an association 19 does not establish a causal relationship? 20 MR. FARIES: Objection to form. 21 THE WITNESS: Okay. That is what we 22 always -- one of the first things we teach 23 students, that correlation is not causation. 24 BY MR. HEGARTY: 25 Q. And is correlation and association the</p>	<p style="text-align: right;">Page 145</p> <p>1 MR. FARIES: I'm sorry, is this not a good 2 breaking point now? 3 MR. HEGARTY: Oh, yeah. No, we can do a 4 breaking point. We can do it now. 5 MR. FARIES: Yeah, let's do it now. 6 (RECESS TAKEN FROM 12:28 P.M. TO 1:30 P.M.) 7 BY MR. HEGARTY: 8 Q. Dr. Moorman, when you do a case-control 9 study, you adjust for confounders that are also risk 10 factors that you believe may have an effect on the 11 results of the study, correct? 12 A. Yes, we consider confounders, yes. 13 Q. Is a confounder the same thing as a risk 14 factor? 15 MR. FARIES: Objection to form. 16 THE WITNESS: A confounder is a factor 17 that is associated with the outcome and is also 18 associated with the exposure that you're 19 interested in. So it should have some -- it 20 should be associated with the outcome. 21 BY MR. HEGARTY: 22 Q. Your intent when you do studies is to 23 adjust for all risk factors that are -- could be 24 associated with the outcome, correct? 25 MR. FARIES: Objection to form.</p>

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<p style="text-align: right;">Page 146</p> <p>1 THE WITNESS: I do want to make that a 2 little bit more nuanced. We -- our objective is 3 to consider them. Sometimes when you do the 4 analysis you might do it in an iterative process 5 and so you might consider a factor as a 6 potential confounder. If it does not change the 7 overall association, you may not necessarily 8 keep that in your final statistical model. 9 BY MR. HEGARTY: 10 Q. But you agree that in papers where you 11 have been an author and looking at -- at risk factors 12 for ovarian cancer that you have not included as a 13 confounder body powder use, correct? 14 MR. FARIES: Objection to form. 15 THE WITNESS: I don't believe that is an 16 absolute accurate statement. I think that we 17 may have considered it. As I said, it may not 18 have -- if we put it into a model and it made no 19 difference, then there would be no need to 20 adjust for it. 21 BY MR. HEGARTY: 22 Q. Did the paper reflect whether you 23 considered it, that is body powder use as a risk 24 factor, and decided not to adjust for it? 25 A. It -- I can't say that with absolute</p>	<p style="text-align: right;">Page 148</p> <p>1 results section. Do you see that? 2 A. Yes. 3 Q. The first line there says: (Reading) 4 As expected, established 5 ovarian cancer risk factors differ 6 between cases and controls. 7 You cite the Table 1, correct? 8 A. Yes. 9 Q. You did not include in Table 1 body powder 10 exposure as an established ovarian cancer risk factor, 11 correct? 12 A. No, Dr. Terry did not include that in this 13 table. 14 Q. You did not recommend that she include 15 that in this table either, did you? 16 MR. FARIES: Objection to form. 17 THE WITNESS: No, I did not make that 18 recommendation. 19 BY MR. HEGARTY: 20 Q. That's all I have as to that study. 21 MR. KLATT: I'm sorry, what was that 22 exhibit? 23 MR. HEGARTY: 8. 24 MS. PARFITT: 8. 25 MR. FARIES: You write that on there?</p>
<p style="text-align: right;">Page 147</p> <p>1 certainty. It is typical to describe the factors that 2 you considered as risk factors. 3 Q. I'm going to hand you what I marked as 4 Exhibit Number 8. 5 A. Okay. 6 (EXHIBIT NUMBER 8 WAS MARKED FOR IDENTIFICATION) 7 MR. FARIES: Thank you. 8 BY MR. HEGARTY: 9 Q. This is a paper in which you were a 10 coauthor on entitled, Supplemental Selenium May 11 Decrease Ovarian Cancer Risk in African-American 12 Women. Is that correct? 13 A. Yes. 14 Q. This was published -- well, it says at the 15 bottom: (Reading) 16 Manuscript received 17 October 20, 2016; initial review 18 completed November 23rd, 2016; 19 revisions accepted January 17th, 2017. 20 Correct? 21 A. That is correct. 22 Q. Then it notes it was first published 23 online on February 15, 2017, correct? 24 A. Correct. 25 Q. If you turn over to page 2 under the</p>	<p style="text-align: right;">Page 149</p> <p>1 MR. KLATT: Do you want me to? On the 2 article? 3 MR. HEGARTY: Yeah, on the article itself. 4 (EXHIBIT NUMBER 9 WAS MARKED FOR IDENTIFICATION) 5 BY MR. HEGARTY: 6 Q. I'm going to show you what I've marked as 7 Exhibit 9. This is another paper in which you were an 8 author on, correct? 9 A. Yes. 10 Q. That paper is entitled, Analgesic 11 Medication Use and Risk of Epithelial Ovarian Cancer 12 in African-American Women. Correct? 13 A. Yes. 14 Q. If you look over on page 823, Tables 2 15 and 3 and even Table 1 did not include body powder or 16 talcum powder use as a confounder that was adjusted 17 for, correct? 18 (WITNESS REVIEWS DOCUMENT) 19 A. That is correct. 20 Q. Did you recommend to the author, Lauren 21 Peres, that they include talcum powder use or body 22 powder use as a potential confounder to consider in 23 this -- this analysis? 24 A. I do not recall that I did that, no. 25 Q. And why would you not have made that</p>

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<p>1 recommendation?</p> <p>2 A. I don't know exactly what my thought</p> <p>3 process would have been. In this paper, Dr. Peres is</p> <p>4 a post-doc under the direction of Dr. Schildkraut and</p> <p>5 many times in this situation, the coauthors are not</p> <p>6 involved in every decision along the way and so I</p> <p>7 don't know the entire thought process that they went</p> <p>8 through when they decided which factors they were</p> <p>9 going to use including their statistical model.</p> <p>10 Q. Well, when you say "they," you're one of</p> <p>11 the listed authors, right?</p> <p>12 A. I am one of the listed authors, yes.</p> <p>13 Q. You read that paper and signed off on it</p> <p>14 before it was published, correct?</p> <p>15 A. Yes.</p> <p>16 Q. You had the ability in that paper and in</p> <p>17 the paper we just looked at, Exhibit Number 8, to</p> <p>18 recommend adjustment for other risk factors, correct?</p> <p>19 MR. FARIES: Objection to form.</p> <p>20 THE WITNESS: That is correct.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q. You did not do so as it relates to body</p> <p>23 powder or talcum powder use, correct?</p> <p>24 A. No, I did not.</p> <p>25 Q. This -- these papers use the same study</p>	<p>1 MR. FARIES: Thank you.</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q. This is another paper in which you are an</p> <p>4 author, correct?</p> <p>5 A. That is correct.</p> <p>6 Q. This is a paper whose lead author is</p> <p>7 Bo Qin; is that correct?</p> <p>8 A. Yes.</p> <p>9 MR. KLATT: Mark, do you mind reading the</p> <p>10 title?</p> <p>11 MR. HEGARTY: Yeah, just a second.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. The title of that paper is, Dietary</p> <p>14 Quality and Ovarian Cancer Risk in African-American</p> <p>15 Women, correct?</p> <p>16 A. That is correct.</p> <p>17 Q. If you turn over to -- first of all, if</p> <p>18 you look at this paper, first page it said it was</p> <p>19 accepted for publication on June 8th, 2016, correct?</p> <p>20 A. Yes.</p> <p>21 Q. If you turn over to page 1282 under the</p> <p>22 section, Statistical Analysis. Do you see that</p> <p>23 section?</p> <p>24 A. Yes, I do.</p> <p>25 Q. Towards the bottom of the second full</p>
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<p>1 population that you have been working from, the North</p> <p>2 Carolina and/or the African-American study, in which</p> <p>3 you do have information as far as body powder use,</p> <p>4 correct, right?</p> <p>5 MR. FARIES: Objection to form.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q. And you stand behind every word that's</p> <p>9 published in these papers, correct, as an author?</p> <p>10 MR. FARIES: Objection to form.</p> <p>11 THE WITNESS: I stand behind these papers</p> <p>12 in the -- in the way that authors stand behind</p> <p>13 them. It's -- I did not write every word. In</p> <p>14 fact, I did not write these papers, and I felt</p> <p>15 like overall they were appropriate. The data</p> <p>16 was -- I didn't have objections to how the --</p> <p>17 the data were presented.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. And all the authors, the lead authors, are</p> <p>20 certainly competent and respectable scientists,</p> <p>21 correct?</p> <p>22 A. Yes.</p> <p>23 Q. I'm going to show you what I next marked</p> <p>24 as Exhibit Number 10.</p> <p>25 (EXHIBIT NUMBER 10 WAS MARKED FOR IDENTIFICATION)</p>	<p>1 paragraph it notes that: (Reading)</p> <p>2 The multi-variant adjusted</p> <p>3 model further considered a priority</p> <p>4 the potential confounders or risk</p> <p>5 factors for ovarian cancer of . . .</p> <p>6 And then it lists a number of risk</p> <p>7 factors, correct?</p> <p>8 A. Correct.</p> <p>9 Q. And body powder use is not listed,</p> <p>10 correct?</p> <p>11 A. Correct.</p> <p>12 Q. This paper also did not adjust for body</p> <p>13 powder/talcum powder use, correct?</p> <p>14 A. Correct.</p> <p>15 Q. You, likewise, had the opportunity to make</p> <p>16 that recommendation if you thought that was</p> <p>17 appropriate to do so, right?</p> <p>18 A. Yes.</p> <p>19 Q. And you felt that the paper as presented</p> <p>20 was appropriate, correct?</p> <p>21 MR. FARIES: Objection to form.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. Next paper I'm going to show you is one I</p> <p>25 marked as Exhibit Number 11.</p>

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<p>1 (EXHIBIT NUMBER 11 WAS MARKED FOR IDENTIFICATION)</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q. This is a paper entitled, Socioeconomic</p> <p>4 Status in Relation to the Risk of Ovarian Cancer in</p> <p>5 African-American Women: A Population-Based</p> <p>6 Case-Control Study. Correct?</p> <p>7 A. Correct.</p> <p>8 Q. You're also an author on this study; is</p> <p>9 that right?</p> <p>10 A. Correct.</p> <p>11 Q. If you look in the abstract, about middle</p> <p>12 of the abstract paragraph, it says: (Reading)</p> <p>13 After adjustment for a</p> <p>14 established ovarian cancer risk</p> <p>15 factors.</p> <p>16 Do you see that?</p> <p>17 A. I do.</p> <p>18 Q. What that means is that this paper</p> <p>19 adjusted for established ovarian cancer risk factors,</p> <p>20 correct?</p> <p>21 MR. FARIES: Objection to form.</p> <p>22 THE WITNESS: That's what they state.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. In fact, that's what you state?</p> <p>25 A. Yes.</p>	<p>1 BY MR. HEGARTY:</p> <p>2 Q. Well, my question is a little bit</p> <p>3 different.</p> <p>4 A. Yes, sir.</p> <p>5 Q. Isn't it correct, though, that if you had</p> <p>6 believed at the time these papers were published that</p> <p>7 body powder or talcum powder exposure was an</p> <p>8 established risk factor for ovarian cancer that you</p> <p>9 would have recommended to your fellow authors that</p> <p>10 they adjust for it in the papers?</p> <p>11 MR. FARIES: Objection to form.</p> <p>12 THE WITNESS: I think it would be fair to</p> <p>13 say that it should be considered, yes.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. Well, is it fair to say, though, in answer</p> <p>16 to my question, that if you believed it would have</p> <p>17 been -- it was an established risk factor at the time</p> <p>18 these papers were published that you would have made</p> <p>19 such a recommendation to your coauthors?</p> <p>20 MR. FARIES: Objection to form.</p> <p>21 THE WITNESS: I'm -- I'm not really -- I'm</p> <p>22 not really sure. It's -- as I said many times,</p> <p>23 when we are working in these large groups,</p> <p>24 you -- you may provide input. It -- I might</p> <p>25 have been operating on the assumption that they</p>
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<p>1 Q. Nowhere in this paper did you as an author</p> <p>2 or the other authors adjust for body powder or talcum</p> <p>3 powder exposure, correct?</p> <p>4 A. That is correct.</p> <p>5 Q. So you would have to agree that as of the</p> <p>6 date this paper was published you did not believe that</p> <p>7 body powder exposure or talcum powder exposure was an</p> <p>8 established ovarian cancer risk factor?</p> <p>9 MR. FARIES: Objection to form.</p> <p>10 THE WITNESS: As I have stated before, I'm</p> <p>11 not sure. It's very hard to pinpoint at a</p> <p>12 particular date what my opinion -- what my</p> <p>13 opinion was.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. Well, wouldn't it be a fair statement that</p> <p>16 as of the date of all these four papers we just looked</p> <p>17 at, if you had believed that ovarian -- that body</p> <p>18 powder or talcum powder use was an established ovarian</p> <p>19 cancer risk factor, you would have recommended that</p> <p>20 the -- you and the other authors adjust for it in the</p> <p>21 study findings, correct?</p> <p>22 MR. FARIES: Objection to form.</p> <p>23 THE WITNESS: I -- I did not make that</p> <p>24 recommendation.</p> <p>25</p>	<p>1 had looked at it and perhaps it was not a risk</p> <p>2 factor, but I just don't know exactly what my</p> <p>3 frame of mind was at that point.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. Well, you know better than anyone yourself</p> <p>6 and how you would approach being an author on a paper,</p> <p>7 correct?</p> <p>8 A. Correct.</p> <p>9 Q. Is it your testimony that if you had</p> <p>10 believed that ovarian -- that body powder or talcum</p> <p>11 powder use was an established risk factor that you</p> <p>12 would not have passed that information along to your</p> <p>13 coauthors?</p> <p>14 MR. FARIES: Objection to form and</p> <p>15 mischaracterizes the witness' prior testimony.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. You can answer.</p> <p>18 A. I'm -- I -- I think that I was probably</p> <p>19 relying on my coauthors and I did not make that</p> <p>20 recommendation. That's all I can say.</p> <p>21 Q. Well, are you testifying here today that</p> <p>22 at the time these papers were published you did</p> <p>23 believe that body powder or talcum powder use was an</p> <p>24 established ovarian cancer risk factor?</p> <p>25 MR. FARIES: Objection to form.</p>

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<p style="text-align: right;">Page 158</p> <p>1 THE WITNESS: My testimony is that I have 2 believed for quite some time that talcum powder 3 use is a risk factor for ovarian cancer. 4 BY MR. HEGARTY: 5 Q. Understood, but I'm talking about at the 6 date these papers were published. Is it your 7 testimony that at the date these papers were published 8 that you believed that body powder or talcum powder 9 use was an established risk factor for ovarian cancer? 10 MR. FARIES: Objection to form. 11 THE WITNESS: I would say yes, I did 12 believe it at that point. 13 BY MR. HEGARTY: 14 Q. And that goes back to even the paper that 15 was published in 2015? 16 A. As I have stated before, I have held this 17 position for a while. I don't know exactly at what -- 18 what point I would have said I held it or did not hold 19 it. 20 Q. And it's your testimony that you -- 21 despite you holding that belief, you didn't pass that 22 belief on to your coauthors; is that correct? 23 MR. FARIES: Objection. Sorry. Objection 24 to form, asked and answered multiple times. 25</p>	<p style="text-align: right;">Page 160</p> <p>1 A. That is correct. 2 Q. Is it correct that this first -- this -- 3 this paper, Exhibit 12, is the first time you ever 4 reported in the study in which you were on a relative 5 risk or odds ratio for body powder or talcum powder 6 use in ovarian cancer? 7 A. To the best of my knowledge yes. 8 Q. This is a paper in which you are the lead 9 author, correct? 10 A. That is correct. 11 Q. That means you are responsible for 12 everything in this paper, right? 13 MR. FARIES: Objection to form. 14 THE WITNESS: I wrote this paper, yes. 15 BY MR. HEGARTY: 16 Q. And you stand behind the results of this 17 paper, correct? 18 A. I do. 19 Q. And in this paper you found no association 20 between talcum powder use and ovarian cancer in either 21 of African-American or white women, correct? 22 MR. FARIES: Objection to form. 23 THE WITNESS: In this paper there was not 24 a statistically significant association, that is 25 true.</p>
<p style="text-align: right;">Page 159</p> <p>1 BY MR. HEGARTY: 2 Q. You can answer. 3 A. Okay. 4 MR. FARIES: And let this be the last time 5 that you ask this question, please. 6 THE WITNESS: Okay. No, I did not pass 7 that information along to the coauthors. 8 BY MR. HEGARTY: 9 Q. Okay. Now, you -- in none of the papers 10 that we just looked at was there a reporting of a 11 relative risk or an odds ratio for talcum or body 12 powder use in ovarian cancer, correct? 13 A. That is correct. 14 Q. But you have been an author on several 15 papers that have reported an odds ratio or relative 16 risk for use of talcum powder or body powder -- 17 powders and ovarian cancer, correct? 18 A. That is correct. 19 (EXHIBIT NUMBER 12 WAS MARKED FOR IDENTIFICATION) 20 BY MR. HEGARTY: 21 Q. The first paper, from what I can tell, of 22 your publications that reported an odds ratio or 23 relative risk is what I've marked as Exhibit Number 12 24 which is titled, Ovarian Cancer Risk Factors in 25 African-American and White Women. Correct?</p>	<p style="text-align: right;">Page 161</p> <p>1 BY MR. HEGARTY: 2 Q. Well, with regard to white women, the odds 3 ratio you reported is 1.04, correct? 4 A. That is correct. 5 Q. That is essentially null value, right? 6 MR. FARIES: Sorry, hang on, slow down. 7 Objection to form. 8 MR. HEGARTY: Okay. 9 MR. FARIES: Now you can proceed. 10 THE WITNESS: Okay. Among the white 11 women, that is correct, the odds ratio was 1.04, 12 which is very close to the null value. 13 BY MR. HEGARTY: 14 Q. You also compared the results in whites 15 and African-American women and found no difference 16 between the two, correct? You did not find 17 heterogeneity, right? 18 A. If you let me just look for a moment to -- 19 Q. Sure. 20 A. -- just recall. 21 MR. FARIES: If you don't feel 22 comfortable, always review your paper. 23 (WITNESS REVIEWS DOCUMENT) 24 THE WITNESS: Uh-huh. That is correct, we 25 did not find a statistically significant</p>

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<p>1 interaction between race and talc use in this 2 particular paper. 3 BY MR. HEGARTY: 4 Q. What that means is, in sort of layperson 5 terms, is that you didn't find a difference in the 6 risk of ovarian cancer in white women using talc and 7 in black women using talc? 8 A. I do want to put that in the -- we do have 9 to keep in mind the statistical -- that was a 10 statistical measure and the statistical measures are 11 always dependent on sample size, and so in this case 12 we did have a relatively small group of 13 African-Americans and so our tested interaction was 14 not statistically significant, and that is not to say 15 with certainty that there was no difference because 16 that test is dependent on sample size. 17 Q. You did have enough cases and controls in 18 order to do an odds ratio, though, correct? I'll let 19 that -- let me -- let me rephrase that. 20 You don't contend that there was not 21 sufficient power in the study in order to evaluate the 22 risk of ovarian cancer with talcum powder use, do you? 23 MR. FARIES: Objection to form. 24 THE WITNESS: When -- this study, the 25 North Carolina Ovarian Cancer Study, was</p>	<p>1 Q. -- how many cases and controls did you 2 have? 3 A. Okay. When you look at the data here, 4 it's up at the -- the column headings, it tells you we 5 had 746 white cases, 868 controls, 111 6 African-American cases, and similar number of 7 controls, and then for the talc use, you'll note that 8 there was missing data for quite a few of them. So I 9 guess we are looking at 600-plus white cases and only 10 about 83 African-American cases. 11 Q. You agree, though, you had enough cases -- 12 enough cases and controls in order to -- to do an odds 13 ratio? 14 MR. FARIES: Objection to form. 15 THE WITNESS: One can calculate an odds 16 ratio with a very small number of cases and 17 controls so . . . 18 BY MR. HEGARTY: 19 Q. You agree you had enough cases and 20 controls and results in order to report them in this 21 study, correct? 22 A. I -- yes, we did. 23 Q. And there -- there have been times when 24 you've published a paper where you said in the paper 25 you didn't feel like you had enough cases and controls</p>
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<p>1 intended to look at many different risk factors 2 for ovarian cancer. When the study was 3 designed, it was not specifically designed to be 4 powered to detect the association specifically 5 with talc. Talc was one of many risk factors 6 that was considered in this study. 7 BY MR. HEGARTY: 8 Q. You have over 300 cases and over 300 9 controls, correct? 10 A. I'm -- I'm -- 11 MR. FARIES: Objection to form. 12 BY MR. HEGARTY: 13 Q. I'm sorry. In your -- I'm sorry. 14 You have -- for a number of cases in the 15 study you had -- well, how many number of cases did 16 you have? Let me ask you. 17 A. Okay. 18 MR. FARIES: I'm sorry, which part of the 19 study? 20 MR. HEGARTY: Right, fair point. 21 THE WITNESS: Okay. 22 BY MR. HEGARTY: 23 Q. With regard to the talc use section on 24 Table 2 -- 25 A. Okay.</p>	<p>1 in order to present the data, correct? 2 A. That is correct. 3 Q. You did not find that to be the case with 4 this study, correct? 5 MR. FARIES: Objection to form. 6 BY MR. HEGARTY: 7 Q. You can answer. 8 A. Okay. No, we obviously -- we did report 9 odds ratios. 10 Q. You stand behind the results of this 11 study, correct? 12 A. I do. 13 Q. And is it safe to say that you did not 14 have the opinions that you're offering here today back 15 when you did this study, correct? 16 MR. FARIES: Objection to form. 17 THE WITNESS: I want to emphasize, once 18 again, that the opinions are formed not on one 19 single study, that they were not based just on 20 this study, my opinion was not based on this, 21 and I think that it is also very important to 22 bear in mind that this study was published 2009, 23 so about nine years ago. There has been an 24 accumulation of additional data that has 25 informed my opinion since then.</p>

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<p style="text-align: right;">Page 166</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. Fair enough. And my question was limited</p> <p>3 to the time this paper was published back in 2009, and</p> <p>4 that question was, it's correct that you did not hold</p> <p>5 the opinions that you've expressed here today back in</p> <p>6 2009 when this paper was published, correct?</p> <p>7 MR. FARIES: Objection to form.</p> <p>8 THE WITNESS: Once again, I think it --</p> <p>9 that I have said it repeatedly that my opinions</p> <p>10 have evolved with the accumulation of more data</p> <p>11 as any scientist would. And at any point in</p> <p>12 time, it's impossible to say specifically what</p> <p>13 was my opinion. Obviously, we did want to</p> <p>14 investigate talc as a risk factor for ovarian</p> <p>15 cancer.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. This 2009 paper did not show that talc use</p> <p>18 increased the risk of ovarian cancer, correct?</p> <p>19 A. As we -- I stated before, it did not show</p> <p>20 a significantly increased risk in either of the racial</p> <p>21 groups we examined.</p> <p>22 Q. The results are consistent with no</p> <p>23 increased risk with talc use, correct?</p> <p>24 MR. FARIES: Objection to form.</p> <p>25 THE WITNESS: As we have discussed about</p>	<p style="text-align: right;">Page 168</p> <p>1 as Exhibit 13 is a paper entitled, Primary Peritoneal</p> <p>2 and Ovarian Cancers: An Epidemiological Comparative</p> <p>3 Analysis. This is another paper in which you are an</p> <p>4 author on, correct?</p> <p>5 A. That is correct.</p> <p>6 Q. This paper --</p> <p>7 MR. KLATT: Mark, what year is that?</p> <p>8 MR. HEGARTY: This paper was --</p> <p>9 MR. FARIES: 2010.</p> <p>10 MR. HEGARTY: -- received November 18,</p> <p>11 2009; accepted February 10, 2010; published</p> <p>12 online March 23rd, 2010.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q. In this paper you looked at whether there</p> <p>15 was an association between talc use and serous primary</p> <p>16 peritoneal cancer and serous epithelial ovarian</p> <p>17 cancer, correct?</p> <p>18 A. It has been a while since I have --</p> <p>19 Q. Sure.</p> <p>20 A. -- looked at this paper so . . .</p> <p>21 MR. FARIES: Just take your time.</p> <p>22 THE WITNESS: Okay.</p> <p>23 (WITNESS REVIEWS DOCUMENT)</p> <p>24 Okay.</p> <p>25</p>
<p style="text-align: right;">Page 167</p> <p>1 odds ratios previously, the odds ratio -- or the</p> <p>2 confidence intervals give the range of values</p> <p>3 with which it is statistically compatible, so</p> <p>4 yes, it is compatible with no increased risk,</p> <p>5 it's compatible with a greater risk than what</p> <p>6 was reported as well.</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q. It is also compatible with a decreased</p> <p>9 risk of ovarian cancer with talc use, correct?</p> <p>10 A. Yes.</p> <p>11 MR. FARIES: Objection to form.</p> <p>12 THE WITNESS: Right. It's, again,</p> <p>13 something that is driven in part by the sample</p> <p>14 size we were examining.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q. You certainly didn't include any</p> <p>17 statements in that paper that talc use increases the</p> <p>18 risk of ovarian cancer, correct?</p> <p>19 A. I don't believe that I did, no.</p> <p>20 Q. Did not state that talc use causes ovarian</p> <p>21 cancer, correct?</p> <p>22 A. I did not.</p> <p>23 (EXHIBIT NUMBER 13 WAS MARKED FOR IDENTIFICATION)</p> <p>24 BY MR. HEGARTY:</p> <p>25 Q. Next paper I'm going to show you is marked</p>	<p style="text-align: right;">Page 169</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. Have you had a chance to look at it?</p> <p>3 A. I have refreshed my memory a bit, yes.</p> <p>4 Q. Again, this paper looked at whether there</p> <p>5 was an association between talc use out of the North</p> <p>6 Carolina -- Carolina Ovarian Cancer Study to serous</p> <p>7 primary peritoneal cancer and serous epithelial</p> <p>8 ovarian cancer, correct?</p> <p>9 A. That is correct.</p> <p>10 Q. If you look over at Table 2, do you agree</p> <p>11 that you found no association between talc use and</p> <p>12 serous primary peritoneal cancer and serous -- or</p> <p>13 serous epithelial ovarian cancer?</p> <p>14 MR. FARIES: Objection to form.</p> <p>15 THE WITNESS: Okay. So our reports here</p> <p>16 are an odds ratio below 1 per serous peritoneal</p> <p>17 cancer versus controls, so this one study would</p> <p>18 suggest it was not associated there. And with</p> <p>19 the serous epithelial ovarian cancer, the odds</p> <p>20 ratio was 1.15 and, again, the 95 percent</p> <p>21 confidence interval indicates that that was not</p> <p>22 a statistically significantly increased risk.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. In fact, as to the odds ratio for serous</p> <p>25 primary peritoneal cancer, that is a non-statistically</p>

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<p style="text-align: right;">Page 170</p> <p>1 significant decrease in a risk, correct?</p> <p>2 MR. FARIES: Objection to form.</p> <p>3 THE WITNESS: That -- yes, that odds ratio</p> <p>4 is an inverse association based on a quite small</p> <p>5 sample size.</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q. But what that means is that it's a</p> <p>8 non-statistically significant protective effect,</p> <p>9 correct?</p> <p>10 MR. FARIES: Objection to form.</p> <p>11 THE WITNESS: I would prefer to</p> <p>12 characterize it as an inverse association.</p> <p>13 "Protective" would require some consideration of</p> <p>14 mechanism.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q. But in this study with regard to the</p> <p>17 serous form of epithelial ovarian cancer you found no</p> <p>18 association between talc use and that form of ovarian</p> <p>19 cancer, correct?</p> <p>20 MR. FARIES: Objection to form.</p> <p>21 THE WITNESS: Please say that one more</p> <p>22 time.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. Sure. With regard to the serous form or</p> <p>25 type of ovarian cancer, in this study you found no</p>	<p style="text-align: right;">Page 172</p> <p>1 giving you her epi opinion and she doesn't --</p> <p>2 she's not referring to just that term alone.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. And I guess my question was, why do you</p> <p>5 need to call this finding a non-statistically</p> <p>6 significant -- that you didn't find a</p> <p>7 non-statistically significant association?</p> <p>8 MR. FARIES: Objection to form.</p> <p>9 THE WITNESS: When we look at</p> <p>10 associations, statistical significance is</p> <p>11 certainly one of the things that we consider.</p> <p>12 Okay. Sometimes interesting suggestive findings</p> <p>13 may be reported that are not statistically</p> <p>14 significant and sometimes that is a relation --</p> <p>15 in relation to sample size, and so to say no</p> <p>16 association very strictly speaking, no</p> <p>17 association would mean an odds ratio of 1 and so</p> <p>18 that's why I qualified it as it was not a</p> <p>19 statistically significant association.</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q. Is it your opinion that use of talcum</p> <p>22 powder products increases the risk of serous primary</p> <p>23 peritoneal cancer?</p> <p>24 A. I do not have a well-formed opinion on</p> <p>25 that because primary peritoneal cancers are a fairly</p>
<p style="text-align: right;">Page 171</p> <p>1 association between talc use and that form of ovarian</p> <p>2 cancer, correct?</p> <p>3 MR. FARIES: Objection to form.</p> <p>4 THE WITNESS: Okay. I have already</p> <p>5 answered that. The -- for neither the serous</p> <p>6 primary peritoneal nor the epithelial ovarian</p> <p>7 cancer the results were not statistically</p> <p>8 significantly increased.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q. And that means that in this study you</p> <p>11 found no association, correct?</p> <p>12 A. We did not find a statistically</p> <p>13 significant association.</p> <p>14 Q. Well, is there a non-statistically</p> <p>15 significant association?</p> <p>16 MR. FARIES: Objection to form.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. Why did you qualify my question by saying</p> <p>19 you didn't find a statistically significant</p> <p>20 association? And my follow-up question, is there a</p> <p>21 non-statistically significant association?</p> <p>22 MR. FARIES: She's not qualifying her</p> <p>23 answer. She's asking -- she's answering your</p> <p>24 questions. You want her to just agree to the</p> <p>25 phrase "association" with nothing more and she's</p>	<p style="text-align: right;">Page 173</p> <p>1 small subset of ovarian cancer and there is -- some</p> <p>2 people would consider them a subset of ovarian cancer,</p> <p>3 some would consider them a distinct type of cancer,</p> <p>4 and there is just not enough data to -- to form an</p> <p>5 opinion.</p> <p>6 Q. You stand behind the results of this</p> <p>7 study?</p> <p>8 A. I do.</p> <p>9 Q. In looking at the last two studies, did</p> <p>10 you include those two studies on your list of reliance</p> <p>11 materials that we marked as Exhibit Number 3?</p> <p>12 MR. FARIES: And just to clarify, that's</p> <p>13 Exhibit 12 and 13?</p> <p>14 MR. HEGARTY: Correct.</p> <p>15 MR. FARIES: Okay.</p> <p>16 THE WITNESS: Okay. This one (indicating)</p> <p>17 is on --</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. Which one, 12?</p> <p>20 A. Yes, Exhibit 12, Ovarian Cancer Risk</p> <p>21 Factors in African-American and White Women, American</p> <p>22 Journal of Epidemiology 2009. And it appears that I</p> <p>23 did not include that in the list.</p> <p>24 Q. Why did you not include Exhibit 13?</p> <p>25 A. It was an oversight.</p>

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<p style="text-align: right;">Page 174</p> <p>1 Q. Do you rely on what I've marked as Exhibit 2 Number 13 as part of your reliance materials for your 3 opinions in this case? 4 A. I consider -- you know, as I said, I 5 considered the full body of literature and so, yes. 6 Q. Within the dataset of the North Carolina 7 Ovarian Cancer Study, are there -- is that a racially 8 diverse population; in other words, does it include 9 white women, African-American women, Hispanic women? 10 A. It was -- is a racially diverse. There 11 were no exclusions by race/ethnicity, but it was 12 reflecting the population and the incidence of ovarian 13 cancer, so the vast majority of the -- or a large 14 majority of the women in the study were white women. 15 Q. Do you know what percentage? 16 A. Off the top of my head, I don't know. I 17 would say probably definitely greater than 80 percent. 18 (EXHIBIT NUMBER 14 WAS MARKED FOR IDENTIFICATION) 19 BY MR. HEGARTY: 20 Q. Next study I'm going to hand you I've 21 marked as Exhibit Number 14. This is a study 22 entitled, Racial, slash, Ethnic Differences in the 23 Epidemiology of Ovarian Cancer: A Pooled Analysis of 24 12 Case-Control Studies. 25 A. Yes.</p>	<p style="text-align: right;">Page 176</p> <p>1 MS. PARFITT: Page 8? 2 MR. HEGARTY: Page 8. 3 BY MR. HEGARTY: 4 Q. -- and you look at the section, Body 5 Powder Use. Do you see that section? 6 A. Yes, I do. 7 Q. First of all, body powder use includes use 8 of cornstarch products, correct? 9 A. It may. 10 Q. It can include deodorizing body powders, 11 correct? 12 A. It -- it may, yes. 13 Q. Body powder use is not exclusive to 14 powders containing talcum powder for purposes of the 15 African-American study, correct? 16 MR. FARIES: Objection to form. 17 THE WITNESS: That is correct. 18 BY MR. HEGARTY: 19 Q. In fact, some of the women in the 20 African-American study used only cornstarch products, 21 correct? 22 MR. FARIES: Objection to form. 23 THE WITNESS: We do not know that. We 24 asked about body powder use, so we did not ask 25 them to distinguish.</p>
<p style="text-align: right;">Page 175</p> <p>1 Q. Is that correct? 2 A. That is correct. 3 Q. You are an author on this paper; is that 4 correct? 5 A. That is correct. 6 Q. This paper shows in the upper right-hand 7 corner that it was published on December 2nd, 2017; E 8 published ahead of print; is that correct? 9 A. I'm sorry, where are you? 10 Q. Upper right-hand corner. 11 A. I am not seeing that on the document. 12 Q. I'm sorry, you may have different copy 13 than I have. This is the copy I have. I guess they 14 gave me a different copy. The copy I have shows it 15 was published in December 2nd -- on December 2nd; E 16 published ahead of print. Do you know if that's 17 accurate, if whether it was published in December of 18 2017? 19 A. I don't recall the exact date. I know 20 that it is a paper that came out fairly recently. 21 Q. Do you agree it came out in the last three 22 months, four months? 23 A. That sounds about right. 24 Q. If you turn over to page 8 of this 25 study --</p>	<p style="text-align: right;">Page 177</p> <p>1 BY MR. HEGARTY: 2 Q. But you did not limit it to body powder 3 use containing talcum, correct? 4 A. That is correct. 5 Q. If you look at the column for body powder 6 use, you found that -- you found no increase in the 7 risk of ovarian cancer from any genital use in 8 Hispanic women, correct? 9 MR. FARIES: Objection to form. When 10 you're referring to "you," do you mean the 11 witness literally or the authors of the study? 12 MR. HEGARTY: Fair point. 13 BY MR. HEGARTY: 14 Q. Yeah, the -- when I talk about "you," I'm 15 referring to the paper or the authors. Is that -- do 16 you understand that? 17 A. Right. Once again, I want to say the -- 18 found an odds ratio of 1.41. The confidence interval 19 included 1 so, therefore, it was not a statistically 20 significant increased risk. 21 Q. You also not find a statistically 22 significant increased risk in Asian/Pacific Islander 23 women, correct? 24 A. That is correct. 25 Q. Is it your opinion that the increased risk</p>

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<p style="text-align: right;">Page 178</p> <p>1 of body powder -- of ovarian cancer with body powder 2 use does not vary across racial and ethnicity 3 features? 4 MR. FARIES: Objection to form. 5 BY MR. HEGARTY: 6 Q. Let me ask it a different way. 7 A. Yeah, there were a couple of double. 8 Q. Do you believe -- you've offered the 9 opinions in this case about body powder use in ovarian 10 cancer. Do you -- is it your opinion that those apply 11 regardless of racial or ethnicity characteristics? 12 MR. FARIES: Objection to form. 13 THE WITNESS: Okay. I based my opinion on 14 the overall body of literature, and as all of us 15 are well aware, the body of literature is 16 predominantly white populations. And as we can 17 see here, the number of Hispanic women is a 18 small fraction of the number of non-Hispanic 19 whites and the same is true but to a lesser 20 extent for black women and Asian and Pacific 21 Islanders. And again, my opinion was based on 22 the overall body of literature. This one 23 publication suggests that the strength of the 24 association may vary somewhat across race/ethnic 25 groups, but again, that is for race/ethnic</p>	<p style="text-align: right;">Page 180</p> <p>1 BY MR. HEGARTY: 2 Q. You also found in this study: (Reading) 3 As reported below, no 4 statistically significant association 5 between aspirin, acetaminophen, or 6 NSAID use and ovarian cancer. 7 Correct? 8 A. Again, all of those associations were not 9 statistically significant. 10 Q. If turn over to page 9, top of the second 11 column you say: (Reading) 12 Study heterogeneity was 13 present for several characteristics 14 which include body powder exposure. 15 Correct? 16 A. Let me just -- yes, that is what it 17 states. 18 Q. That means that you found differences in 19 the odds ratios across the various racial groups, 20 correct? 21 A. Yes, that is -- would be -- yes. 22 Q. And if you look down at the bottom of that 23 column, the last paragraph says: (Reading) 24 For a model of established EOC 25 epithelial ovarian cancer risk</p>
<p style="text-align: right;">Page 179</p> <p>1 groups other than non-Hispanic whites. We are 2 somewhat more limited in the numbers. 3 BY MR. HEGARTY: 4 Q. You found in -- you or the paper or the 5 studies found in this analysis that there was no 6 statistically significant association between 7 nongenital use of body powder and ovarian cancer in 8 any racial group, correct? 9 A. As reported here, so in non-Hispanic 10 white, the odds ratio 1, that is an accurate 11 statement. For the Hispanic woman, it is -- 1.55 is 12 the odds ratio. The lower bound of the confidence 13 interval is right at 1 so that would typically 14 translate to a p-value of right at .05, and so at 15 least in that group there is some indication of 16 increased risk. 17 Q. But in that group, the real odds ratio 18 could be 1.00, correct? 19 MR. FARIES: Objection to form. 20 THE WITNESS: We've talked about the 21 interpretation of the odds ratio repeatedly. 22 This is the range of values with which it is 23 statistically compatible. The lower bound of 24 the confidence interval is a possible but less 25 likely value.</p>	<p style="text-align: right;">Page 181</p> <p>1 factors. 2 Then you list several of those risk 3 factors in the -- then you list the risk factors in 4 the parenthetical. Then you state: (Reading) 5 The average ORs among the 6 controls was estimated by race 7 ethnicity. 8 Correct? 9 A. That's what is stated, yes. 10 Q. In this paper you did not include as an 11 established epithelial ovarian cancer risk factor body 12 powder use, correct? 13 MR. FARIES: Objection to form. And just, 14 once again, the "you" is the authors, the 15 collective publication. 16 MR. HEGARTY: That includes her. 17 MR. FARIES: Yes, she's one of authors. 18 THE WITNESS: Okay. Yes, the -- talc was 19 not included in this model. 20 BY MR. HEGARTY: 21 Q. Did you recommend to your fellow authors 22 that talcum powder -- or I'm sorry, that body powder 23 use should be included in the list of established 24 epithelial ovarian cancer risk factors? 25 A. I did not.</p>

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<p style="text-align: right;">Page 182</p> <p>1 Q. And that's what this line says</p> <p>2 when -- strike that.</p> <p>3 When you put the parenthetical -- when the</p> <p>4 authors put the parenthetical after established</p> <p>5 epithelial ovarian cancer risk factors, you intended</p> <p>6 to identify in that parenthetical those the authors</p> <p>7 concluded were established risk factors, correct?</p> <p>8 MR. FARIES: Objection to form.</p> <p>9 THE WITNESS: That is a list of them --</p> <p>10 the factors that they did include in the model,</p> <p>11 yes.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. Well, that they included --</p> <p>14 A. And they --</p> <p>15 Q. I'm sorry.</p> <p>16 A. That they -- the investigators that did</p> <p>17 this statistical analysis, that is what they included</p> <p>18 in that model as -- and they considered the</p> <p>19 established risk factors.</p> <p>20 Q. And the investigators included you?</p> <p>21 A. Yes.</p> <p>22 Q. And then if you turn over to the next</p> <p>23 page, page 10, the very bottom to the right-hand</p> <p>24 column, the authors write: (Reading)</p> <p>25 A concern with self-reported</p>	<p style="text-align: right;">Page 184</p> <p>1 MR. FARIES: Objection to form.</p> <p>2 THE WITNESS: These two sentences are</p> <p>3 definitely raising that as a concern about</p> <p>4 factors like this. They outline some of the</p> <p>5 concerns about how difficult it is to accurately</p> <p>6 report this -- these exposures.</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q. And you stand behind the results of this</p> <p>9 study too, correct?</p> <p>10 A. Yes, I do.</p> <p>11 Q. Now, at the time this study was published,</p> <p>12 you had been retained as an expert for Plaintiffs in</p> <p>13 this litigation, correct?</p> <p>14 A. Let's see, I'm trying to -- this -- yes,</p> <p>15 I -- I think that I must have been.</p> <p>16 Q. Did you have to fill out a conflict of</p> <p>17 interest disclosure as part of this paper?</p> <p>18 A. I don't recall specifically for this</p> <p>19 paper.</p> <p>20 Q. Well, as a matter of course, you have to</p> <p>21 fill out one, correct?</p> <p>22 A. Most journals do.</p> <p>23 Q. Are you ever published in -- in any</p> <p>24 journal that has not required the authors in the last</p> <p>25 few years to provide a conflict of interest</p>
<p style="text-align: right;">Page 183</p> <p>1 data is recall bias especially for</p> <p>2 characteristics that are difficult to</p> <p>3 report with accuracy. Required</p> <p>4 subjective summarization or can be</p> <p>5 influenced by the investigator, media,</p> <p>6 or similar factors. Such problematic</p> <p>7 characteristics may include body</p> <p>8 powder exposure, analgesic medication</p> <p>9 use, breastfeeding, and possibly</p> <p>10 family history.</p> <p>11 Did I read that correctly?</p> <p>12 A. You did read that correctly.</p> <p>13 Q. What the authors are stating there is that</p> <p>14 the results reported could be inaccurate because of</p> <p>15 subjective summarization or the influence by the</p> <p>16 investigator, media, or similar factors, correct, as</p> <p>17 it relates to body powder use, correct?</p> <p>18 MR. FARIES: Objection to form.</p> <p>19 THE WITNESS: Please state --</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q. Sure. What that --</p> <p>22 A. -- the question.</p> <p>23 Q. -- those two sentences state is that</p> <p>24 recall bias could influence the results as it relates</p> <p>25 to body powder use, correct?</p>	<p style="text-align: right;">Page 185</p> <p>1 disclosure?</p> <p>2 A. I can't think of one right offhand. I</p> <p>3 just . . .</p> <p>4 Q. This was published in the International</p> <p>5 Journal of Epidemiology, correct?</p> <p>6 A. Yes.</p> <p>7 Q. That journal requires the authors to</p> <p>8 identify any potential conflicts of interest, correct?</p> <p>9 MR. FARIES: Objection to form.</p> <p>10 THE WITNESS: Once again, I publish in --</p> <p>11 we publish in many journals and I -- I just</p> <p>12 don't specifically recall the conflict of</p> <p>13 interest form for this one.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. Did you disclose to the Journal at the</p> <p>16 time this was published that you were a paid</p> <p>17 Plaintiffs' expert in litigation involving talcum</p> <p>18 powder or body powder use in ovarian cancer?</p> <p>19 A. I did not.</p> <p>20 Q. Don't you believe that an author reading</p> <p>21 this paper with your name on it should know whether</p> <p>22 you're a paid Plaintiffs' expert who's going to</p> <p>23 testify in litigation that body powder use or talcum</p> <p>24 powder use causes ovarian cancer?</p> <p>25 MR. FARIES: Objection to form.</p>

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<p>1 THE WITNESS: Yeah, it is standard. It</p> <p>2 was an oversight on my part.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. It's a pretty significant oversight, don't</p> <p>5 you think?</p> <p>6 MR. FARIES: Objection to form.</p> <p>7 THE WITNESS: I acknowledge that it was an</p> <p>8 oversight.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q. And do the ethical requirements of your</p> <p>11 university, Duke University, require authors to</p> <p>12 disclose if they are paid -- paid Plaintiffs' -- paid</p> <p>13 experts on either side if they publish a paper on the</p> <p>14 very subject matter in which they are offering</p> <p>15 testimony in?</p> <p>16 A. I don't know that Duke has a specific</p> <p>17 policy. I acknowledge that this was an oversight on</p> <p>18 my part.</p> <p>19 Q. If you were going to publish this paper</p> <p>20 today and fill out a conflict of interest form, would</p> <p>21 you disclose that you're a paid Plaintiffs' expert in</p> <p>22 this litigation?</p> <p>23 A. Yes, I would.</p> <p>24 MR. FARIES: We're at an hour point. Is</p> <p>25 this a good --</p>	<p>1 Dr. Schildkraut and I, we designed, applied for</p> <p>2 funding together. And -- and most of the papers, as</p> <p>3 you know from our study, Dr. Schildkraut is the last</p> <p>4 author, the senior author. On this paper she put me</p> <p>5 last just as a way of acknowledging the key role that</p> <p>6 I had in developing this study.</p> <p>7 Q. Now, this study did not report on an</p> <p>8 association between talc use and ovarian cancer,</p> <p>9 correct?</p> <p>10 MR. FARIES: Objection to form.</p> <p>11 THE WITNESS: This paper reported on body</p> <p>12 powder use and ovarian cancer.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q. Body powder use as defined in this paper</p> <p>15 over on page 1412 under exposure to body powder and</p> <p>16 talc included participants who used talc, cornstarch,</p> <p>17 baby or deodorizing powders, correct?</p> <p>18 A. That is correct.</p> <p>19 Q. With regard to cornstarch powders, those</p> <p>20 would not have talc in them, correct?</p> <p>21 MR. FARIES: Objection to form.</p> <p>22 THE WITNESS: Cornstarch powders would not</p> <p>23 contain talc.</p> <p>24 BY MR. HEGARTY:</p> <p>25 Q. Deodorizing powders don't necessarily</p>
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<p>1 MR. HEGARTY: Yeah, that's fine because</p> <p>2 I'm going to move on to the next --</p> <p>3 MR. FARIES: Okay, perfect.</p> <p>4 (RECESS TAKEN FROM 2:24 P.M. TO 2:38 P.M.)</p> <p>5 (EXHIBIT NUMBER 15 WAS MARKED FOR IDENTIFICATION)</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q. Okay. We are back on the record.</p> <p>8 Dr. Moorman, the next study I want to talk</p> <p>9 about is the study that is specifically referenced in</p> <p>10 your disclosure that we talked about earlier in the</p> <p>11 day that I marked as Exhibit Number 15. The paper's</p> <p>12 titled, Association Between Body Powder Use and</p> <p>13 Ovarian Cancer: The African-American Cancer</p> <p>14 Epidemiology Study, correct?</p> <p>15 A. That is correct.</p> <p>16 Q. That is a paper with the lead author being</p> <p>17 Joellen Schildkraut?</p> <p>18 A. That is correct.</p> <p>19 Q. You are also an author, right?</p> <p>20 A. Yes.</p> <p>21 Q. You're listed last. Is there anything</p> <p>22 about the way authors are listed that tells you</p> <p>23 anything about an author that's listed last?</p> <p>24 A. Many times the last author is considered a</p> <p>25 senior author. In this particular paper,</p>	<p>1 contain talc, correct?</p> <p>2 A. No, not necessarily.</p> <p>3 Q. Also, baby powders don't necessarily</p> <p>4 always contain talc, correct?</p> <p>5 A. That -- I believe that is correct.</p> <p>6 Q. So with regard to the data reported as</p> <p>7 shown over in Table 2, you reported the results as far</p> <p>8 as body powder use, not breaking it out between</p> <p>9 cornstarch or deodorizing powder or talcum powder,</p> <p>10 correct?</p> <p>11 A. We did not have that information to break</p> <p>12 it out. It was felt that most women could probably</p> <p>13 not recall with any degree of accuracy whether it was</p> <p>14 cornstarch, whether it was a talc product or a baby</p> <p>15 powder considering how long a period of time we were</p> <p>16 asking about. Other investigators who have broken</p> <p>17 that out have reported that when people were asked</p> <p>18 about it, specifically, there were -- a small</p> <p>19 proportion of the women in the studies reported</p> <p>20 cornstarch use. So it is a fair assumption to say</p> <p>21 that most of the use here would have been a talc-based</p> <p>22 powder.</p> <p>23 Q. Do you list that data anywhere in the</p> <p>24 paper?</p> <p>25 A. The data that -- reported from other</p>

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<p>1 studies that --</p> <p>2 Q. Well, no, the data here as far as -- well,</p> <p>3 strike that.</p> <p>4 Did you -- I thought you indicated that</p> <p>5 with regard to this study, the majority of women you</p> <p>6 are reporting on used talcum powder; is that correct?</p> <p>7 A. We asked them as it -- the question is</p> <p>8 phrased here. We asked them about the use of any body</p> <p>9 powder.</p> <p>10 Q. You did not ask them any question where</p> <p>11 you tried to break out on an individual basis whether</p> <p>12 they had -- which one they had used, correct?</p> <p>13 A. That is correct. The question was not</p> <p>14 phrased in that way.</p> <p>15 Q. So from the data in this study there's no</p> <p>16 way to know if 90 percent used cornstarch or</p> <p>17 90 percent used talcum powder, correct?</p> <p>18 MR. FARIES: Objection to form.</p> <p>19 THE WITNESS: As I stated before, we asked</p> <p>20 about body powder use only, and so we could not</p> <p>21 say what was the specific powder that a woman</p> <p>22 used.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. Over on page 14 -- I'm sorry, going back.</p> <p>25 First page, page 1411, in the paragraph -- sorry, I'm</p>	<p>1 relationship with genital powder use</p> <p>2 for frequency, duration or number of</p> <p>3 applications.</p> <p>4 Do you see that sentence?</p> <p>5 A. I do see that sentence.</p> <p>6 Q. And that sentence after the word "some"</p> <p>7 you, the authors, including you, use the</p> <p>8 parenthetical -- say in the parenthetical 7-15. Does</p> <p>9 that mean you're making a statement that references 7</p> <p>10 through dash 15 found a dose-response relationship</p> <p>11 between genital powder use and ovarian cancer?</p> <p>12 A. That -- that is -- it's -- yes, it's how</p> <p>13 it should be interpreted, typically.</p> <p>14 Q. One of the papers you cite in support of</p> <p>15 that statement is a paper by Mills, Reference 11:</p> <p>16 (Reading)</p> <p>17 Perineal talc exposure and</p> <p>18 epithelial ovarian cancer risk in the</p> <p>19 Central Valley of California.</p> <p>20 Correct?</p> <p>21 A. Yes, that is correct.</p> <p>22 Q. I'm going to mark as Exhibit Number 16</p> <p>23 that paper, Perineal talc exposure in epithelial</p> <p>24 ovarian cancer risk in the Central Valley of</p> <p>25 California.</p>
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<p>1 looking for the particular sentence that I want to</p> <p>2 look at.</p> <p>3 Is it correct that within the study not</p> <p>4 all women reported a dose, that is, whether frequency</p> <p>5 of use, duration of use or both?</p> <p>6 MR. FARIES: I'm sorry, where are you</p> <p>7 referring?</p> <p>8 THE WITNESS: Yeah, I'm not sure.</p> <p>9 MR. HEGARTY: I could not find the</p> <p>10 specific reference, so I switched to a different</p> <p>11 question.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. Did all the women in this study report</p> <p>14 on -- provide data on dose either by duration,</p> <p>15 frequency or both?</p> <p>16 A. All of the women were asked about -- asked</p> <p>17 how frequently they used it and for how many years.</p> <p>18 I'm -- there may have been some that did not answer</p> <p>19 those questions or said they didn't know.</p> <p>20 Q. In that last paragraph on page 411 you</p> <p>21 include the sentence, starting the third line that:</p> <p>22 (Reading)</p> <p>23 Some, but not all previous</p> <p>24 published studies of talc and ovarian</p> <p>25 cancer reported a dose-response</p>	<p>1 (EXHIBIT NUMBER 16 WAS MARKED FOR IDENTIFICATION)</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q. This is the paper that you're citing to in</p> <p>4 Reference 11, correct?</p> <p>5 A. Yes.</p> <p>6 Q. If you look in the abstract of that paper,</p> <p>7 two-thirds of the way down, do you see where the</p> <p>8 authors report that no dose-response association was</p> <p>9 found?</p> <p>10 A. I see what they reported there. And I</p> <p>11 also -- in this paper in Table 2 they report the</p> <p>12 frequency of use and report a significant p-value for</p> <p>13 trend. They report a significant p-value for duration</p> <p>14 of use. And then for the cumulative use, the duration</p> <p>15 by frequency, the p-value is .051, so right at the</p> <p>16 borderline of statistical significance. So I think</p> <p>17 that the statement that -- yeah, the inclusion of this</p> <p>18 paper as one that found a -- let's see -- a</p> <p>19 dose-response relationship for frequency, duration or</p> <p>20 number of applications, that appears to be accurate.</p> <p>21 Q. Despite that the author is saying in the</p> <p>22 paper that there's -- there was no dose-response</p> <p>23 association, right?</p> <p>24 MR. FARIES: Objection to form.</p> <p>25 THE WITNESS: I think on the basis of the</p>

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<p>1 data that's presented in the -- in the table, 2 that this was not an inaccurate statement 3 despite what the authors -- that statement in 4 the abstract. 5 BY MR. HEGARTY: 6 Q. You also cited in support of that 7 statement the Wong paper called, Perineal talc 8 exposure and subsequent epithelial ovarian cancer, a 9 case-control study, correct? 10 MR. FARIES: Reference Number 13? 11 MR. HEGARTY: Reference 13. 12 THE WITNESS: Yes. 13 BY MR. HEGARTY: 14 Q. I'm going to mark as Exhibit 17 that 15 reference. 16 (EXHIBIT NUMBER 17 WAS MARKED FOR IDENTIFICATION) 17 BY MR. HEGARTY: 18 Q. Is that the paper that you're referring to 19 in Reference 13? 20 A. Yes, it is. 21 Q. If you look in the results section of the 22 abstract about a third of the way down, the authors 23 state: (Reading) 24 A significant association 25 between duration of talc use and</p>	<p>1 and that is indeed cited so . . . 2 Q. You also cite in that same paragraph the 3 2016 paper by Dr. Cramer, correct? 4 A. I'm sorry, which reference number? 5 Q. It is Reference 15. 6 A. And so in -- again, which statement are we 7 referring to? 8 Q. I'm at the top of page 1412, first full 9 paragraph -- 10 A. Okay. 11 Q. -- where you're referring to his finding 12 with regard to an association with genital talc use in 13 his African-American population. 14 A. Okay. If you have that paper here, it 15 would be nice to look at that one. You're correct 16 that it was cited. 17 Q. I only have two copies so I'll -- 18 A. Okay. 19 Q. -- mark the other copy I have and let you 20 share. 21 A. Okay. 22 (EXHIBIT NUMBER 18 WAS MARKED FOR IDENTIFICATION) 23 BY MR. HEGARTY: 24 Q. Exhibit 18 is the paper, The Association 25 Between Talc Use and Ovarian Cancer: A Retrospective</p>
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<p>1 development of epithelial ovarian 2 cancer was not demonstrated both for 3 one to nine years, for 10 to 15 -- 4 10 to 19 years or for more than 5 20 years. 6 Correct? 7 A. That is correct. 8 Q. Can you find anywhere in that paper where 9 they report a statistically significant dose response? 10 MR. FARIES: Objection to form. 11 THE WITNESS: I do not. So, apparently, 12 that was cited incorrectly in that regard. 13 BY MR. HEGARTY: 14 Q. Okay. If you turn over to the next page, 15 top left-hand corner, you cite in the carryover in the 16 first full paragraph there some studies that have 17 looked at in the past the risk of ovarian cancer and 18 genital powder use, correct? 19 A. Correct. 20 Q. You did not cite to your 2009 or 2010 21 papers, correct? 22 A. I did -- those papers were not cited. 23 However, I do want to point out that the North -- the 24 data from the North Carolina ovarian cancer study was 25 included in the pooled analysis done by Terry, et al.,</p>	<p>1 Case-Control Study in Two States; is that correct? 2 A. That is correct. 3 Q. That is the paper that you cited in that 4 paragraph that we've been talking about at the top of 5 page 1412? 6 A. Let's see. Okay. 7 Q. Did you say yes? 8 A. Yes. 9 Q. You cited in that paragraph an odds ratio 10 reported in that paper of 5.08 with a confidence 11 interval of 1.32 to 19.6. Do you see that in the 12 paper? 13 A. Yes. 14 Q. Is it your opinion that that's an accurate 15 odds ratio for African-American women exposed to body 16 powder use? 17 MR. FARIES: Objection to form. 18 THE WITNESS: That odds ratio, I believe 19 that was what was reported in this paper, and as 20 was noted in our paper, it was based on a very 21 small sample of 16 cases and 17 controls. And 22 so it's -- I think that that number is too small 23 that say -- to say -- you know, that number of 24 cases and controls is to say that that is an 25 accurate representation among all</p>

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<p>1 African-Americans. You couldn't make that</p> <p>2 judgment based on only that few women.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. Would you turn over in the Schildkraut</p> <p>5 paper, what we marked as Exhibit Number 15, to</p> <p>6 Table 2, please?</p> <p>7 A. Yes.</p> <p>8 Q. In that table under body powder use by</p> <p>9 location, the second column you broke down the</p> <p>10 reported odds ratios by interviews -- interview date,</p> <p>11 before 2014 and after 2014, correct?</p> <p>12 A. That is correct.</p> <p>13 Q. That was done to look at the potential</p> <p>14 effect of the results on the participants' knowledge</p> <p>15 of lawsuits filed concerning talcum powder use and</p> <p>16 ovarian cancer, correct?</p> <p>17 A. Yes, that was done at a suggestion of a</p> <p>18 manuscript reviewer.</p> <p>19 Q. Who was the manuscript reviewer?</p> <p>20 A. The reviewers are anonymous.</p> <p>21 Q. Your results -- sorry, strike that.</p> <p>22 The results of that breakout between the</p> <p>23 before 2014 and after 2014 are listed in this table,</p> <p>24 correct?</p> <p>25 A. That is correct.</p>	<p>1 MR. FARIES: Objection to form.</p> <p>2 Go ahead.</p> <p>3 THE WITNESS: When we consider that,</p> <p>4 it's -- chance is always a potential</p> <p>5 consideration. We considered the possibility</p> <p>6 that there was recall bias. And there's also</p> <p>7 the possibility that knowing about these</p> <p>8 lawsuits might have triggered some memories that</p> <p>9 women really hadn't thought about. So it -- the</p> <p>10 possibilities range from recall bias to truly</p> <p>11 more accurate recall because they were aware of</p> <p>12 it.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q. Are you aware, Dr. Moorman, of the</p> <p>15 significant advertisements that have ran across the</p> <p>16 country for -- by Plaintiffs' lawyers with regard to</p> <p>17 talc and ovarian cancer cases?</p> <p>18 MR. FARIES: Objection to form.</p> <p>19 THE WITNESS: I have seen advertisements</p> <p>20 on TV. I -- I don't know how widely they were</p> <p>21 broadcast, in what markets, what channels.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. You do agree that it's possible given --</p> <p>24 strike that.</p> <p>25 You agree that in the face of publicity</p>
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<p>1 Q. If you just look at the data for interview</p> <p>2 date before 2014, there was no statistically</p> <p>3 significant association found, correct, for body</p> <p>4 powder use as it relates to any genital use, interview</p> <p>5 date before 2014?</p> <p>6 A. Yes. The confidence intervals include</p> <p>7 one, so that odds ratio 1.40 and 1.19, they were not</p> <p>8 statistically significant.</p> <p>9 Q. As to interviews after 2014 the odds ratio</p> <p>10 went from 1.19 to 2.91 with a statistically</p> <p>11 significant confidence interval, correct?</p> <p>12 A. That is correct.</p> <p>13 Q. And if you look at the reported percentage</p> <p>14 of -- of talc users, any genital use, before 2014 they</p> <p>15 report -- reported number was 36.5 percent and the</p> <p>16 reported number after that date of 2014 was 51.14,</p> <p>17 correct? In the cases?</p> <p>18 A. That is correct.</p> <p>19 Q. If you look at the controls, the reported</p> <p>20 use of genital powder was 34 percent before 2014 and</p> <p>21 34.4 percent after 2014, correct?</p> <p>22 A. That is correct.</p> <p>23 Q. How do you account for an increase only in</p> <p>24 the cases of 15 percent just based on the interview</p> <p>25 date?</p>	<p>1 between an exposure and a disease that such publicity</p> <p>2 can be to such an extent that you cannot do an</p> <p>3 accurate retrospective case-control study? Do you</p> <p>4 agree that that's a true statement?</p> <p>5 MR. FARIES: Objection to form.</p> <p>6 THE WITNESS: I don't agree that -- I</p> <p>7 cannot agree that that is an accurate statement,</p> <p>8 because I do not know the extent to which</p> <p>9 advertising our knowledge about it would --</p> <p>10 would bias the results.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. Well, I'm talking in a hypothetical</p> <p>13 situation where there is awareness across the given</p> <p>14 group of a link, supposed link, between an exposure</p> <p>15 you're looking at and a disease. Is it your opinion,</p> <p>16 in that environment, you could do an accurate</p> <p>17 case-control study like this?</p> <p>18 MR. FARIES: Objection to form. Also</p> <p>19 objection as to an incomplete ill-defined</p> <p>20 hypothetical.</p> <p>21 THE WITNESS: I would have to say it</p> <p>22 depends on the exposure and the outcome.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. Is there, in a hypothetical situation, a</p> <p>25 level of an exposure and an outcome in which you would</p>

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<p>1 agree that it would be impossible to do a case control 2 study that would report accurate results? 3 MR. FARIES: Objection to form. 4 THE WITNESS: I could not state what 5 level, what degree, what that would be to say 6 that we could not do a case-control study. 7 BY MR. HEGARTY: 8 Q. You do agree it would be a significant 9 concern in such an environment? 10 MR. FARIES: Objection to form. 11 THE WITNESS: Anytime we do a case-control 12 study we consider recall bias as a concern. 13 BY MR. HEGARTY: 14 Q. But you would consider a concern publicity 15 or awareness of your study group between an exposure 16 and a disease you're looking at, correct? 17 A. Yes, we would, which would play into 18 recall bias, why might women recall differently. 19 Q. As you said, recall bias could explain the 20 difference between the number of cases who reported 21 body powder use before 2014 and the number that 22 reported afterwards, after 2014? 23 MR. FARIES: Objection to form. 24 THE WITNESS: I said that that was one 25 possible explanation.</p>	<p>1 correct? Under duration of use? 2 MR. FARIES: I'm sorry, objection to the 3 form of the question. 4 THE WITNESS: And the test for trend for 5 duration of use was not statistically 6 significant for the nongenital use. Yes, that 7 is correct. 8 BY MR. HEGARTY: 9 Q. With regard to the -- any genital use by 10 number of applications, you use the levels of less 11 than 3600 and greater than 3600. How did those -- how 12 were those levels chosen? 13 A. That was the median number of 14 applications. That was the cut point used. 15 Q. Is it correct that you did not -- or 16 strike that. 17 Did you find any dose response for only 18 nongenital use in ovarian cancer? 19 A. We did not find a significant trend with 20 either duration of use nor with number of applications 21 for nongenital use. 22 Q. You also found no increase in risk of 23 ovarian cancer -- I'm sorry, strike that. 24 For occupational exposures you found no 25 increase in risk of ovarian cancer, correct?</p>
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<p>1 BY MR. HEGARTY: 2 Q. Now, you looked at dose response in this 3 study, correct? 4 A. Yes, we considered that. 5 Q. You found -- you reported on a dose 6 response for only any powder use, correct? 7 MR. FARIES: What table are we looking at? 8 MR. HEGARTY: I'm sorry, for -- let me 9 back -- let me break that up. I'm still 10 Table 2. 11 MR. FARIES: All right. 12 THE WITNESS: Okay. 13 BY MR. HEGARTY: 14 Q. For duration you found no dose response in 15 any group, correct? 16 A. Okay. We are looking at Table 2 -- 17 Q. Duration of use. 18 A. -- in duration of use. So the women who 19 reported it for less than 20 years, 1.33, for greater 20 than 20 years the odds ratio was 1.52 with a 21 significant p-value for trend. So that does indicate 22 a significant trend with duration of use for any 23 genital use. 24 Q. You did not find one for -- you're not 25 finding dose response for only nongenital use,</p>	<p>1 A. I'm trying to remember where we reported 2 that in the paper. Right. In the paragraph below 3 that we report an odds ratio of 1.31. And the 4 confidence interval does include one, so it was not 5 statistically significant. And as I recall, that was 6 a pretty small number of women who reported 7 occupational use. 8 Q. Did you also report in this study that you 9 found that most studies show no association to 10 nongenital use? 11 A. I think that we did make that statement in 12 here. 13 Q. Did you make a statement anywhere in this 14 paper that body powder use causes ovarian cancer? 15 A. No, I did not make -- no, that statement 16 was not made in this paper. 17 Q. Can you cite for me any epidemiologic 18 study where the authors determined a statistically 19 significant increase in risk of talcum powder use in 20 ovarian cancer that exceeded 2.0? 21 MR. FARIES: Objection to the form. 22 THE WITNESS: I -- I'm sorry, tell me 23 again. 24 BY MR. HEGARTY: 25 Q. Sure. Can you cite for me any</p>

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<p style="text-align: right;">Page 206</p> <p>1 epidemiologic study where the authors determined a 2 statistically significant increase in risk greater 3 than two between perineal talc use and ovarian cancer? 4 MR. FARIES: Objection to form. 5 THE WITNESS: Okay. We have already 6 talked about one instance of that. In the 7 Cramer paper it was greater than two for the 8 sample of African-American women. But, again, 9 we have talked about the imprecision of that 10 estimate based on the small sample size. 11 And I -- I know that there have -- other 12 studies have reported a relative risk greater 13 than two. I do not recall on the individual 14 studies if it was statistically significant 15 right off the top of my head. 16 BY MR. HEGARTY: 17 Q. Are you aware of any paper where the 18 authors reported an overall increase in risk that's 19 statistically significant in excess of two between 20 perineal talc use and ovarian cancer? 21 A. So my answer is the same as for the last 22 question that there have been some papers that have 23 reported an odds ratio greater than two but off the 24 top of my head, I don't recall whether or not they 25 were statistically significant.</p>	<p style="text-align: right;">Page 208</p> <p>1 A. No, I have not. 2 Q. Have you ever done the kind of analysis 3 you've done here with regard to talcum powder product 4 use in ovarian cancer where you've been paid by 5 plaintiffs' lawyers? 6 A. No, I have never done anything like that. 7 Q. Have you ever done any kind of analysis 8 like you've done here where you've reviewed deposition 9 testimony and other materials generated in litigation? 10 A. No, I have not. 11 Q. Have you ever done any type of analysis 12 like you've done here for any cosmetic other than 13 talcum powder products? 14 A. No, I have not. 15 Q. How about with regard to any other mineral 16 besides talcum powder? 17 A. No, I have not. 18 Q. In terms of the process you've talked 19 about in reaching your opinions in this case, have you 20 ever published in any peer-reviewed publication the 21 steps that you took here to come to your opinions? 22 MR. FARIES: Objection to form. 23 THE WITNESS: Have I ever described the 24 steps I took to evaluate talc and ovarian 25 cancer?</p>
<p style="text-align: right;">Page 207</p> <p>1 Q. Dr. Moorman, have you ever -- strike that. 2 Dr. Moorman, before being contacted by 3 Plaintiffs' lawyers in this case, had you ever done 4 any type of analysis, review and come to opinions as 5 you have done here in any situation involving any 6 exposure or any disease? 7 MR. FARIES: Objection to form. 8 THE WITNESS: I think that every time we 9 write a paper, we are considering all of the 10 data and coming to an opinion, so I would argue 11 that I have done that many times. 12 BY MR. HEGARTY: 13 Q. Have you ever done the same analysis 14 here -- strike that. 15 Have you ever done analysis like you did 16 here and came to the conclusion that any other 17 exposure caused or causes any other disease? 18 A. I have never used the phrasing "cause." I 19 have certainly used the phrasing "increased risk." 20 Q. Have you ever done an analysis looking at 21 either an increased risk -- looking at either 22 increased risk or cause where you've received 23 materials from a plaintiff's lawyer? 24 A. Other than this case? 25 Q. Yes.</p>	<p style="text-align: right;">Page 209</p> <p>1 BY MR. HEGARTY: 2 Q. Yes. In any published, peer-reviewed 3 piece of literature? 4 A. I have not. 5 MR. FARIES: Objection to form. 6 BY MR. HEGARTY: 7 Q. I'm sorry, what was the answer? 8 A. I said I have not. 9 Q. Other than -- strike that. 10 In terms of -- Dr. Moorman, do you agree 11 that all women are at risk for developing ovarian 12 cancer? 13 MR. FARIES: Objection to form. 14 THE WITNESS: I would say that all women 15 who have ovaries are at risk for developing 16 ovarian cancer. 17 BY MR. HEGARTY: 18 Q. With regard to women who have ovaries, 19 what is their lifetime risk of developing ovarian 20 cancer? 21 A. That is typically reported as about a 1.3 22 to 1.4 lifetime probability. 23 Q. Ovarian cancer existed before any talcum 24 powder product was ever used by women, correct? 25 A. Yes.</p>

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<p>1 Q. Ovarian cancer would still exist if women 2 stopped using talcum powder products, correct? 3 A. Yes. 4 Q. Ovarian cancer occurs in women who have 5 never been exposed to any talcum powder product, 6 correct? 7 A. Yes. 8 Q. And any woman who used a talcum powder 9 product was still at risk for ovarian cancer without 10 regard to the use of the talcum powder products, 11 correct? 12 A. Yes. 13 Q. And there are women who develop ovarian 14 cancer who have no known risk factors, correct? 15 MR. FARIES: Objection to form. 16 THE WITNESS: Yes. 17 BY MR. HEGARTY: 18 Q. And as to all of the women in this case, 19 if you had been able to talk to them at a young age, 20 you could not have assured them that they would not 21 get ovarian cancer if they never used a talcum powder 22 product, correct? 23 MR. FARIES: Objection to form. 24 THE WITNESS: You could not assure them of 25 that because ovarian cancer is not caused by one</p>	<p>1 defined mutation in, like, BRCA1 or BRCA2. And so 2 it's contrasting those -- the genetic -- the strong 3 genetic association versus the ones without that. 4 Q. If a woman's lifetime risk generally is 5 1.3 to 1.4, what is the lifetime risk of a woman who 6 uses talcum powder products? 7 MR. FARIES: Objection to form. 8 THE WITNESS: We are talking about the 9 relative risk. Most of the meta-analyses 10 conclude that there is a relative risk of about 11 1.25, so multiplying 1.4 by 1.25 gives you a 12 lifetime risk of approximately 1.7 percent, 13 something like that. When -- and, of course, 14 when you apply it to millions of women, that 15 small difference becomes more important. 16 BY MR. HEGARTY: 17 Q. What is the latency period by which use of 18 talcum powder products can cause ovarian cancer? 19 MR. FARIES: Objection to form. 20 THE WITNESS: It is usually very difficult 21 to establish with precision what the latency 22 period is for any given exposure. Many times it 23 is thought that the latency period can be many 24 decades. 25</p>
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<p>1 single risk factor. 2 BY MR. HEGARTY: 3 Q. So no single risk factor can be the cause 4 of an ovarian cancer; is that what -- that what you're 5 saying? 6 A. No, I am -- I am not saying that. I am 7 saying that there is no single risk factor that 8 accounts for all ovarian cancers. 9 Q. Ovarian cancer occurs even in the absence 10 of risk factors, correct? 11 MR. FARIES: Objection to form. 12 THE WITNESS: Ovarian cancer, something 13 has to cause it, okay? And so it is accurate to 14 say that sometimes it occurs in the absence of 15 known risk factors. 16 BY MR. HEGARTY: 17 Q. That cause can be what's considered to be 18 sporadic, correct? 19 MR. FARIES: Objection to form. 20 BY MR. HEGARTY: 21 Q. Do you know what the phrase "sporadic 22 cause" means? 23 A. In the epidemiology world, most often when 24 the term "sporadic" is used, it is used to contrast it 25 with, like, a genetic cause or, like, for example, a</p>	<p>1 BY MR. HEGARTY: 2 Q. Well, do you have an opinion as to how 3 long a woman must use a talcum powder product for it 4 to be a -- for it to cause ovarian cancer? 5 MR. FARIES: Objection to form. 6 THE WITNESS: For an individual woman, I 7 would not have an opinion, and I also do not 8 think that we have the data that we could say -- 9 we could say that how many applications, how 10 long is too much. I don't think we can identify 11 any safe period of use. 12 BY MR. HEGARTY: 13 Q. All right. Do you have the data to have 14 an opinion as to how long talcum powder products must 15 be used or how frequent they must be used in order to 16 actually increase the risk of ovarian cancer in a 17 woman? 18 MR. FARIES: Objection to form. 19 THE WITNESS: I think my answer is just 20 like for the previous question, that we don't 21 have that data. 22 BY MR. HEGARTY: 23 Q. What is the volume of talcum powder 24 exposure necessary to either cause or increase the 25 risk of ovarian cancer?</p>

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<p>1 MR. FARIES: Objection to form.</p> <p>2 THE WITNESS: We do not have the data to</p> <p>3 say what would cause -- what a safe level would</p> <p>4 be.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q. With regard to asbestos exposure, I'll ask</p> <p>7 the same questions. Do you have an opinion as to how</p> <p>8 long or how much or how frequent a woman would need to</p> <p>9 be exposed to asbestos to either increase their risk</p> <p>10 or cause ovarian cancer?</p> <p>11 MR. FARIES: Objection to form.</p> <p>12 THE WITNESS: I don't think that we can</p> <p>13 say any defined cut point. I think that it is</p> <p>14 very important to rely on the conclusion of the</p> <p>15 various organizations that have concluded that</p> <p>16 there's no safe level of asbestos exposure,</p> <p>17 so . . .</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. Is there a background level of asbestos in</p> <p>20 the air?</p> <p>21 MR. FARIES: Objection to form.</p> <p>22 THE WITNESS: I don't know. That's not my</p> <p>23 area of expertise.</p> <p>24 BY MR. HEGARTY:</p> <p>25 Q. In your -- with regard to developing your</p>	<p>1 Some studies reported on that, some did not, and I</p> <p>2 considered all of the data.</p> <p>3 Q. But did you break out your opinions based</p> <p>4 on odds ratios across the various types of ovarian</p> <p>5 cancers?</p> <p>6 A. To some extent. Serous ovarian cancer is</p> <p>7 the vast or the largest subtype of ovarian cancer, and</p> <p>8 among studies that have looked at that, there seems to</p> <p>9 be an indication that the risk may be higher for that</p> <p>10 subtype than for others. For the other subtypes, they</p> <p>11 comprise a much smaller proportion of ovarian cancers,</p> <p>12 and so, again, we run into the numbers game. It is</p> <p>13 harder to make a conclusion within the smaller</p> <p>14 subgroups.</p> <p>15 Q. Did you try to make a conclusion within</p> <p>16 the smaller subgroups?</p> <p>17 A. I considered the data, but I felt like</p> <p>18 there was not adequate data to make as strong of a</p> <p>19 conclusion as with the serous subtype or the overall</p> <p>20 ovarian cancer.</p> <p>21 Q. Well, did you draw -- did you come to any</p> <p>22 conclusions based on the data where you stratified by</p> <p>23 sub -- across all subtypes? You said that the studies</p> <p>24 did not -- or the data did not provide as strong of a</p> <p>25 conclusion. Did you actually, though, break out your</p>
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<p>1 opinions, did you break down your opinion by subtype</p> <p>2 of ovarian cancer?</p> <p>3 MR. FARIES: I'm sorry? Which --</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. With regard to your opinions in this case,</p> <p>6 did you break down your opinions based on subtype of</p> <p>7 ovarian cancer?</p> <p>8 A. So by that you are talking -- please --</p> <p>9 Q. Sure.</p> <p>10 A. -- specify.</p> <p>11 Q. For purpose of your opinions in this case,</p> <p>12 are they the same for all subtypes, serous, clear</p> <p>13 cell, endometrioid, mucinous?</p> <p>14 A. Okay.</p> <p>15 MR. FARIES: Objection to form.</p> <p>16 THE WITNESS: I considered the full body</p> <p>17 of literature, and some studies did report by</p> <p>18 subtypes, some did not, and so the forming of my</p> <p>19 opinion did consider some of that published</p> <p>20 data.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q. In your analysis did you attempt to</p> <p>23 stratify the extent of risk based on type of ovarian</p> <p>24 cancer?</p> <p>25 A. Again, I was relying on published data.</p>	<p>1 odds ratios or relative risk calculations by subtype</p> <p>2 of ovarian cancer?</p> <p>3 MR. FARIES: Objection to form.</p> <p>4 THE WITNESS: Once again, I considered all</p> <p>5 of the data and considered that the data for</p> <p>6 some of the smaller subtypes was not as strong</p> <p>7 as for -- the data, just because it's reflecting</p> <p>8 smaller samples sizes, was not as strong as --</p> <p>9 based on the other serous subtype or the overall</p> <p>10 ovarian cancer.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. Well, are you applying the 1.25 to 1.3</p> <p>13 relative risk you provided across all subtypes?</p> <p>14 A. So when I refer to the 1.25, that is the</p> <p>15 conclusion that has been reached in multiple</p> <p>16 meta-analyses, and the meta-analyses looked at -- most</p> <p>17 of them did not look at the subtypes. More recent</p> <p>18 meta-analysis did look at it by some of the subtypes</p> <p>19 and reported a significant association if I'm</p> <p>20 recalling with the serous subtype.</p> <p>21 Q. Do you agree that the vast majority of</p> <p>22 ovarian cancers have no known cause?</p> <p>23 MR. FARIES: Objection to form.</p> <p>24 THE WITNESS: I do not agree with that</p> <p>25 statement. I think that we have identified many</p>

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<p style="text-align: right;">Page 218</p> <p>1 risk factors for ovarian cancer, and probably</p> <p>2 the majority of women have at least one of those</p> <p>3 risk factors.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. You agreed earlier that a risk factor is</p> <p>6 not necessarily a causal factor, correct?</p> <p>7 A. Yes, I did agree with that.</p> <p>8 Q. If tissue is exposed to talc, talcum</p> <p>9 powder products, what is -- what reaction do you see</p> <p>10 in that tissue?</p> <p>11 MR. FARIES: Objection to form.</p> <p>12 THE WITNESS: Okay. I am not a</p> <p>13 pathologist. I am not a laboratory scientist.</p> <p>14 I have never done that, so I could not describe</p> <p>15 that.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. Can you cite for me any study that is</p> <p>18 reported -- that was reported what tissue looks</p> <p>19 like -- strike that.</p> <p>20 Can you cite for me any study that has</p> <p>21 reported on what ovarian tissue looks like when</p> <p>22 exposed to talcum powder products?</p> <p>23 MR. FARIES: Objection to form.</p> <p>24 THE WITNESS: I cannot off the top of my</p> <p>25 head, no, I cannot cite a specific study.</p>	<p style="text-align: right;">Page 220</p> <p>1 majority of them reported an odds ratio greater than</p> <p>2 1, and many of them reported statistically significant</p> <p>3 associations as well.</p> <p>4 Let's see. I considered the temporality</p> <p>5 and felt confident that the talc exposure preceded</p> <p>6 ovarian cancer consistently across the studies.</p> <p>7 I considered whether or not there were</p> <p>8 biologically plausible mechanisms, and I -- you know,</p> <p>9 I considered the other ones, such as coherence analogy</p> <p>10 experiment as well, but I think my opinion was driven</p> <p>11 by the ones that I've described in more detail.</p> <p>12 Q. So would it be a fair statement from what</p> <p>13 you just said that your opinions was driven -- were</p> <p>14 driven by strength of association, consistency of the</p> <p>15 association, temporality, and biologic plausibility?</p> <p>16 A. Those were the main drivers, but did also</p> <p>17 consider coherence experimentation and analogy.</p> <p>18 MR. FARIES: We're approaching another</p> <p>19 hour. If you have a good transition point --</p> <p>20 MR. HEGARTY: I was going to walk through</p> <p>21 the -- those Bradford Hill criteria next.</p> <p>22 MR. FARIES: Again?</p> <p>23 MR. HEGARTY: You would say again. I</p> <p>24 would say for the first time, but that's where</p> <p>25 I'm going to go next.</p>
<p style="text-align: right;">Page 219</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. You talked a little bit earlier about the</p> <p>3 Bradford Hill guidelines, correct?</p> <p>4 A. I did.</p> <p>5 Q. Did you apply the Bradford Hill guidelines</p> <p>6 in developing your opinions in this case?</p> <p>7 A. I did.</p> <p>8 Q. Did you apply all nine of the Bradford</p> <p>9 Hill guidelines?</p> <p>10 A. I considered all of them and, again,</p> <p>11 emphasizing that this is not a checklist that you</p> <p>12 check off all of them.</p> <p>13 Q. Which of those Bradford Hill guidelines</p> <p>14 were you able to check off?</p> <p>15 A. So, again, I would not characterize what I</p> <p>16 did as checking off any of them. I considered</p> <p>17 strength of the association, and my conclusion from</p> <p>18 that is that the strength of the association was in</p> <p>19 the same range as other factors that have -- that are</p> <p>20 generally accepted as carcinogens. And so the</p> <p>21 strength of the association is -- is adequate.</p> <p>22 I considered the consistency of the</p> <p>23 association, looking at the overall body of the</p> <p>24 epidemiologic literature, including the meta-analyses,</p> <p>25 and found that the majority of the studies, the vast</p>	<p style="text-align: right;">Page 221</p> <p>1 MR. FARIES: Let's take a quick break</p> <p>2 then.</p> <p>3 MR. HEGARTY: Okay.</p> <p>4 MR. FARIES: That will take you a few</p> <p>5 minutes to do that.</p> <p>6 MR. HEGARTY: Oh, yeah. No, it's a new --</p> <p>7 it's a transition point.</p> <p>8 (RECESS TAKEN FROM 3:31 P.M. TO 3:39 P.M.)</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q. Dr. Moorman, we have talked about strength</p> <p>11 in association. I just have a couple of follow-up</p> <p>12 questions.</p> <p>13 Have you ever published in any</p> <p>14 peer-reviewed literature a standard description of how</p> <p>15 you characterize relative risk as, for example, weak,</p> <p>16 moderate, strong? Have you ever done any -- have you</p> <p>17 ever tried to categorize ranges of relative risk</p> <p>18 within some sort of set criteria?</p> <p>19 A. I have not, and I do not believe that it's</p> <p>20 a standard within epidemiology.</p> <p>21 Q. What would you, typically, call a relative</p> <p>22 risk of 1.25 to 1.3?</p> <p>23 MR. FARIES: Objection to form.</p> <p>24 BY MR. HEGARTY:</p> <p>25 Q. If I were to use the categories of weak</p>

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<p style="text-align: right;">Page 222</p> <p>1 and moderate, strong, or you can use your own 2 categories. 3 MR. FARIES: Objection to form. 4 THE WITNESS: I think that it would be 5 probably categorized as modest to moderate 6 association. We do always want to consider that 7 the strength -- the public health importance of 8 an exposure depends not only on the strength of 9 the association but how common is the exposure 10 in the population. 11 BY MR. HEGARTY: 12 Q. You mentioned a little bit ago that the 13 strength of association was consistent with other 14 exposures where -- where causality had also been 15 determined. Can you give me one example? 16 A. One example of that would be secondhand 17 smoke. I can give more if needed. 18 Q. Can you give me a -- give me a few? Give 19 me whatever other examples you have. 20 MR. FARIES: Objection to form. 21 BY MR. HEGARTY: 22 Q. Go ahead. 23 MR. FARIES: Go ahead. 24 THE WITNESS: Other examples may be oral 25 contraceptive use in relation to breast cancer;</p>	<p style="text-align: right;">Page 224</p> <p>1 (EXHIBIT NUMBER 19 WAS MARKED FOR IDENTIFICATION) 2 MAN SPEAKER: What was 18? 3 MR. FARIES: 18 -- here is 18. 4 MAN SPEAKER: Okay. 5 BY MR. HEGARTY: 6 Q. Doctor, would you look at Exhibit 19 and 7 tell me whether you're familiar with that paper? 8 A. I have read this paper, yes. 9 Q. If you turn over to the second page, 10 Figure 1 is a forest plot of case-control studies 11 reported on by Langseth, et al., correct? 12 A. Yes, that is correct. 13 Q. Figure 1 breaks out the case-control 14 studies between the population-based studies and the 15 hospital-based studies, correct? 16 A. That is correct. 17 Q. Do you agree with -- do you agree that 18 every one of the hospital-based case-control studies 19 failed to show a statistically significant association 20 between talc use and ovarian cancer? 21 A. Yes, all of those confidence intervals 22 include one. 23 Q. The authors also did a pooled odds ratio 24 for the hospital-based studies and reported a 25 nonsignificant association, correct?</p>
<p style="text-align: right;">Page 223</p> <p>1 estrogen, menopausal estrogen use, in relation 2 to breast cancer; residential radon exposure in 3 relation to lung cancer. 4 BY MR. HEGARTY: 5 Q. I want to talk next about the consistency 6 factor you mentioned. In doing so I want to look at 7 that factor as it relates to a particular study and 8 that is a study by Langseth from 2008. This would be 9 Exhibit 21, thank you for reminding me. The 10 exhibit -- this copy has a Ness exhibit on the top -- 11 MR. FARIES: Okay. 12 BY MR. HEGARTY: 13 Q. -- you can ignore that. 14 MR. FARIES: Okay. 15 BY MR. HEGARTY: 16 Q. The paper is 2008 by Langseth entitled, 17 Perineal Use of Talc and Risk of Ovarian Cancer. 18 MR. FARIES: I'm sorry, I'm sorry. I 19 think we're incorrect on the -- 20 MR. HEGARTY: Numbering is wrong? 21 MS. PARFITT: Is it 19? 22 MR. HEGARTY: I'm sorry, you're right. It 23 should be 19. I plucked off -- thank you for 24 correcting that, I'm plucked off 21, it should 25 be 19. Thank you for catching that.</p>	<p style="text-align: right;">Page 225</p> <p>1 A. That is correct. 2 Q. And with regard to the hospital-based 3 studies, because they were not statistically 4 significant all of those results, all of the odds 5 ratios, could be due to chance, correct? 6 MR. FARIES: Objection to the form. 7 THE WITNESS: Okay. Yes, all of those 8 because of the -- of the confidence interval 9 including one, it is conceivable that these 10 findings are due to chance. 11 BY MR. HEGARTY: 12 Q. Do you agree that just looking at the 13 hospital-based case-control studies that they do not 14 show an increased risk of ovarian cancer with talc 15 use? 16 MR. FARIES: Objection to the form. 17 THE WITNESS: Okay. Looking at the 18 summary odds ratio it is not statistically 19 significant, and I agree that three of them have 20 reported odds ratios to very close to -- to one. 21 BY MR. HEGARTY: 22 Q. Overall, if we just looked at the 23 hospital-based case-control studies and no other 24 studies, you could not draw the conclusion that there 25 was a causal association between talc use and ovarian</p>

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<p>1 cancer, correct?</p> <p>2 MR. FARIES: Objection to form.</p> <p>3 THE WITNESS: Okay. On the basis of only</p> <p>4 these six studies we would not conclude that.</p> <p>5 We would also consider the -- the overall design</p> <p>6 and potential limitations of some of these</p> <p>7 studies.</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q. For purposes of your opinions in this</p> <p>10 case, did you consider the hospital-based case-control</p> <p>11 studies?</p> <p>12 A. I considered the overall body of evidence,</p> <p>13 yes.</p> <p>14 Q. That overall body would have included the</p> <p>15 hospital-based studies?</p> <p>16 A. Yes.</p> <p>17 Q. Above that analysis of the hospital-based</p> <p>18 studies are the population-based studies they looked</p> <p>19 at in this study, correct?</p> <p>20 A. Yes, those are their population-based</p> <p>21 studies.</p> <p>22 Q. Some of the population-based studies found</p> <p>23 a statistically significant odds ratio and some did</p> <p>24 not, correct?</p> <p>25 A. That is correct.</p>	<p>1 evidence is insufficient to establish</p> <p>2 a causal association between perineal</p> <p>3 use of talc and ovarian cancer risk.</p> <p>4 Did I read that correctly?</p> <p>5 A. Yes, you did read that correctly.</p> <p>6 Q. Is it your opinion that that statement was</p> <p>7 inaccurate when it was made in this publication and</p> <p>8 published in 2008?</p> <p>9 MR. FARIES: Objection to form.</p> <p>10 THE WITNESS: I think that this is the</p> <p>11 statement that these investigators concluded.</p> <p>12 This was ten years ago, and I think that quite a</p> <p>13 lot of data has accumulated since.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. From your experience being in this field</p> <p>16 for 20 plus years, was that statement a reasonable</p> <p>17 statement to make back in 2008?</p> <p>18 MR. FARIES: Objection to form.</p> <p>19 THE WITNESS: I think that, as we have</p> <p>20 said before, that scientists may review a body</p> <p>21 of evidence and come to a different conclusion.</p> <p>22 When we look at the overall odds ratios, it is</p> <p>23 certainly indicative of significantly increased</p> <p>24 risk. And, you know, I don't know how these</p> <p>25 authors took into account other things that</p>
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<p>1 Q. The authors then did a test for</p> <p>2 heterogeneity between the population-based studies and</p> <p>3 the hospital-based studies, correct?</p> <p>4 A. They did. They did report that.</p> <p>5 Q. The test was statistically significant,</p> <p>6 correct?</p> <p>7 A. Yes, they report a p-value of .036.</p> <p>8 Q. That means they found the two groups were</p> <p>9 different, correct?</p> <p>10 A. Yes.</p> <p>11 Q. Do you recall reading the Langseth paper</p> <p>12 when it came out?</p> <p>13 A. I don't remember exactly when I read it.</p> <p>14 Q. Had you read the Langseth paper before</p> <p>15 being contacted by Plaintiffs' counsel in this case?</p> <p>16 A. Once again, I don't recall exactly when I</p> <p>17 read it.</p> <p>18 Q. If you look under the section on the page</p> <p>19 we're looking with the forest plot, under proposal,</p> <p>20 the research community? Do you see that section?</p> <p>21 A. Yes.</p> <p>22 Q. The first one under that section reads:</p> <p>23 (Reading)</p> <p>24 The current body of</p> <p>25 experimental and epidemiologic</p>	<p>1 would play into assessing causality.</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q. Do you know any of these authors</p> <p>4 personally?</p> <p>5 A. I believe that I have met Dr. Hankinson at</p> <p>6 a grant review or something at some time in the past.</p> <p>7 And the other names I do not know these people</p> <p>8 personally.</p> <p>9 Q. Is it your testimony in this case that the</p> <p>10 statement I just read to you at the time it was made</p> <p>11 was wrong? Was inaccurate?</p> <p>12 MR. FARIES: Objection to form.</p> <p>13 THE WITNESS: I am saying that that is the</p> <p>14 statement that they made at that point in time</p> <p>15 based on their opinions.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. Understood. But are we going to hear from</p> <p>18 you at trial that the -- this statement I just read to</p> <p>19 you, at the time it was made back in 2008 was</p> <p>20 inaccurate, was incorrect?</p> <p>21 MR. FARIES: Objection to form.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. In your opinion?</p> <p>24 A. It -- again, we have considered the</p> <p>25 association between talc and ovarian cancer over many</p>

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<p>1 decades, and many papers have come out, and, you know,</p> <p>2 they continue to come out. And so it would -- I</p> <p>3 don't -- I can't say at one point whether I would</p> <p>4 consider this accurate or inaccurate. It's like just</p> <p>5 over time the evidence continues to evolve. And I</p> <p>6 can't say at any given point where I would say with</p> <p>7 absolute certainty that I said this was a cause versus</p> <p>8 this . . . just leave it there.</p> <p>9 Q. I'm going to show you what I'm next</p> <p>10 marking as Exhibit Number 20 which is a 2017 paper by</p> <p>11 Berge, et al., called, Genital Use of Talc and Risk of</p> <p>12 Ovarian Cancer: A Meta-analysis.</p> <p>13 (EXHIBIT NUMBER 20 WAS MARKED FOR IDENTIFICATION)</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. Have you seen this paper before right now?</p> <p>16 A. Yes, I have.</p> <p>17 Q. Did you review this paper at the time it</p> <p>18 was published earlier in 2017?</p> <p>19 A. Yes, I -- yes, I saw it shortly after it</p> <p>20 was published.</p> <p>21 Q. If you look over on page 7, Figure 2, in</p> <p>22 the forest plot on that page, the authors do a</p> <p>23 meta-analysis of the cohort studies only, correct?</p> <p>24 A. That is correct.</p> <p>25 Q. You have reviewed all of the cohort</p>	<p>1 in fact, reported a statistically significantly</p> <p>2 association with serous ovarian cancer. So it would</p> <p>3 not be accurate to say that none of them have</p> <p>4 reported.</p> <p>5 Q. I will come back to that just -- in a</p> <p>6 second.</p> <p>7 Is it a correct statement that as to an</p> <p>8 overall risk of ovarian cancer with talcum powder use</p> <p>9 that none of the cohort studies found an association?</p> <p>10 MR. FARIES: Objection to form.</p> <p>11 THE WITNESS: Once again, none of them</p> <p>12 reported a statistically significantly increased</p> <p>13 risk.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. With regard to the serous finding from the</p> <p>16 Nurses' Health Study from the Gertig 2000 paper, did</p> <p>17 you review the follow-up study that was published by</p> <p>18 Gates in 2010?</p> <p>19 A. I have looked at all of those papers.</p> <p>20 Q. And do you recall that Gates in 2010</p> <p>21 reported a non-statistically significant relative risk</p> <p>22 for the serous type in talcum powder use?</p> <p>23 A. I do recall that.</p> <p>24 Q. That was in a follow-up study that was</p> <p>25 done approximately ten years after -- published ten</p>
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<p>1 studies listed there, correct?</p> <p>2 A. Yes, I have.</p> <p>3 Q. The author in that -- the authors in that</p> <p>4 meta-analysis concluded or came up with a relative</p> <p>5 risk of 1.02 with non-statistically significant</p> <p>6 confidential interval for the cohort studies, correct?</p> <p>7 A. That is correct, that's what they report.</p> <p>8 Q. Do you agree that if you look at the</p> <p>9 cohort studies only, they do not report a</p> <p>10 statistically significant association between talc use</p> <p>11 and ovarian cancer?</p> <p>12 A. That is correct.</p> <p>13 Q. That's even from your own conclusions,</p> <p>14 correct?</p> <p>15 MR. FARIES: Objection to form.</p> <p>16 THE WITNESS: I'm sorry?</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. Sure. Let me repeat it.</p> <p>19 You have looked at all of the cohort</p> <p>20 studies, correct?</p> <p>21 A. I have.</p> <p>22 Q. Do you agree that none of the cohort</p> <p>23 studies show a statistically significant association</p> <p>24 between talc use and ovarian cancer?</p> <p>25 A. I think that the Nurses' Health Study has,</p>	<p>1 years after the original study, correct?</p> <p>2 A. Correct.</p> <p>3 Q. So if we look at -- strike that.</p> <p>4 With regard to the cohort studies and the</p> <p>5 risk of -- reported -- risk reported as to talc use in</p> <p>6 ovarian cancer, generally, those studies were</p> <p>7 uniformly non-statistically significant, correct?</p> <p>8 A. That is correct.</p> <p>9 Q. If we looked -- we looked at the</p> <p>10 hospital-based case-control studies, and those studies</p> <p>11 were uniformly non-statistically significant between</p> <p>12 talcum powder use and ovarian cancer, correct?</p> <p>13 A. That is correct.</p> <p>14 Q. As to the population-based case-control</p> <p>15 studies, those are mixed -- have mixed results with</p> <p>16 regard to statistical significance between ovarian</p> <p>17 cancer -- I'm sorry, between talcum powder use and</p> <p>18 ovarian cancer, correct?</p> <p>19 A. Individual studies are mixed. The summary</p> <p>20 odds ratios from them are statistically significant.</p> <p>21 Q. There's a quote in the Bradford Hill paper</p> <p>22 where he identifies the criteria or categories or</p> <p>23 whatever you might call them, he says: (Reading)</p> <p>24 I would myself put a great</p> <p>25 deal of weight upon similar results</p>

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<p>1 reached in quite different ways, 2 prospectively and retrospectively. 3 Do you recall him making that statement in 4 the paper? 5 A. I don't recall every word of that paper 6 so . . . 7 Q. Do you happen to recall that, if that 8 statement -- 9 A. I don't. 10 Q. -- is accurate? 11 A. I don't recall. As I said, I don't recall 12 that statement, specifically, from that paper. 13 Q. Well, do you agree that with regard to 14 talcum powder use and ovarian cancer, that prospective 15 and retrospective studies do not reach similar 16 results? 17 MR. FARIES: Objection to form. 18 THE WITNESS: I -- I think that one has to 19 look at it in a more nuanced perspective. 20 BY MR. HEGARTY: 21 Q. Well, is it your opinion that the 22 prospective and retrospective studies reached similar 23 results? 24 A. In subsequent meta-analyses there are 25 definitely some areas of similarity that particularly</p>	<p>1 cohort studies are consistent with the retrospective 2 studies? 3 MR. FARIES: Objection to form. 4 THE WITNESS: I -- I believe that the -- 5 the conclusions are different, yes. 6 BY MR. HEGARTY: 7 Q. You believe that -- so the answer to my 8 question is they are not consistent? 9 MR. FARIES: Objection to form. 10 THE WITNESS: I think that we have to 11 think about it, the consistency, in terms of the 12 overall odds ratio. They -- they are somewhat 13 inconsistent. 14 BY MR. HEGARTY: 15 Q. So with that statement in mind, how is it 16 you concluded under the Bradford Hill criteria that 17 there was a consistency or that the consistency factor 18 had been satisfied? 19 A. The -- the cohort studies are three of 20 more than like two dozen studies. And when we look at 21 the overall direction of the effect, we do see a great 22 deal of consistency. Whenever we consider studies 23 that have a different finding, one would want to look 24 at that and try to understand what is different about 25 that study. And very notably here when we look at the</p>
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<p>1 related to the cohort studies that reported on the 2 serous ovarian cancer. 3 Q. How about with respect to the overall risk 4 of ovarian cancer with talcum powder use, is it your 5 testimony that the prospective and retrospective 6 studies are consistent? 7 MR. FARIES: Objection to form. 8 THE WITNESS: I -- my testimony is that 9 stronger associations were observed in the 10 retrospective studies than in the -- the cohort 11 studies. 12 BY MR. HEGARTY: 13 Q. Well, that's not -- my question was, do 14 you -- is it your opinion or testimony that with 15 regard to the overall risk reported between talcum 16 powder use and ovarian cancer, that the prospective or 17 cohort studies are consistent with the retrospective 18 studies? 19 MR. FARIES: I'm going to object to form. 20 THE WITNESS: So say it -- please say it 21 one more time. 22 BY MR. HEGARTY: 23 Q. Sure. Is it your opinion that with regard 24 to the reporting of the overall risk between ovarian 25 cancer and talc powder use, that the prospective or</p>	<p>1 Gonzalez study, they report a relative risk of .73. 2 And that, certainly, brings down the overall relative 3 risk for the cohort studies. 4 The Gonzalez studies has a number of 5 limitations in relation to the evaluation of this 6 exposure and outcome. Most notably -- but there are 7 two very notable ones. Despite it being a reasonably 8 large cohort there were only about 150 cases in that 9 study, and so the statistical power was limited, you 10 know, again, somewhat related to the duration of 11 follow-up in that study. But more significantly when 12 they assessed the exposure, they asked women about 13 their use of talc in the previous 12 months. So, 14 basically, there is a snapshot of exposure. So it did 15 not capture any exposure before they enrolled in the 16 study nor in the time after the questionnaire was 17 completed. So the exposure assessment in that study 18 is clearly inadequate. 19 And so, you know, you just have to 20 consider that the one study that comes up with really 21 a value that's an outlier there may be some very good 22 reasons why it doesn't fit in with nearly all the 23 other studies. 24 Q. In looking at the biologic plausibility 25 analysis under Bradford Hill that you did in this</p>

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<p style="text-align: right;">Page 238</p> <p>1 case, is it your opinion that a biologic mechanism has 2 been proven for talcum powder use causing ovarian 3 cancer? 4 MR. FARIES: Objection to form. 5 THE WITNESS: I would not use the 6 terminology "proven," because I feel like there 7 are very few things that are proven in science. 8 It's the state of knowledge now is -- gives us 9 some clear indications of why talc could lead to 10 ovarian cancer. But, you know, science is 11 always evolving we learn -- as we learn more and 12 more it will continue to evolve. 13 BY MR. HEGARTY: 14 Q. Do you have an opinion as to the possible 15 biologic plausibility of talcum powder use causing 16 ovarian cancer? 17 A. I do. 18 Q. What is it? 19 A. My opinion is that it is biologically 20 plausible that talc exposure could cause ovarian 21 cancer. 22 Q. Through what mechanism? 23 A. Once again, I'm going to go back to my 24 disclaimer that I am not a cancer biologist. But it 25 seems that the most plausible mechanisms would be an</p>	<p style="text-align: right;">Page 240</p> <p>1 increased oxidative stress and 2 increased cytokine levels. 3 Q. In developing your opinions for this case 4 I believe you said you did not review all the 5 genotoxicity studies looking at talc in ovarian 6 cancer, correct? 7 A. Yes, that is correct. 8 Q. I believe you also said that you did not 9 review the cytotoxicity studies looking at talc and 10 ovarian cancer, correct? 11 A. That is correct. 12 Q. But you also said you didn't look at the 13 animal studies that have examined talc and ovarian 14 cancer and the effects of talc on animals, correct? 15 A. I believe when you asked me those 16 questions earlier today, you asked me if I had 17 reviewed all of these studies, and I said no to those 18 questions. I have read some studies, but not all of 19 them. 20 Q. Have you done an exhaustive review of all 21 the animal studies looking at exposure to talc? 22 A. I cannot say that it was an exhaustive 23 review, I have looked at some. Again, that is 24 somewhat out of my area of expertise as an 25 epidemiologist.</p>
<p style="text-align: right;">Page 239</p> <p>1 inflammation pathway. And so through either upward 2 migration of the talc particles to the ovaries, that 3 that could create a -- an environment of chronic 4 inflammation. And in that situation that can lead to 5 the production of reactive oxygen species and other 6 cellular components that could cause damage to DNA and 7 lead to cancer development. 8 Q. In reaching your opinions as to biologic 9 plausibility -- well, first of all, let me back up. 10 Have you ever published, lectured or 11 otherwise made the statement outside of litigation 12 about the mechanism that you just discussed? 13 MR. FARIES: Objection to form. 14 THE WITNESS: Okay. In this paper that we 15 published we do refer that inflammation is a 16 potential mechanism by which ovarian cancer 17 could result from exposure to talc. 18 BY MR. HEGARTY: 19 Q. That's the 2016 Schildkraut paper? 20 A. I believe so. Yes, in the introduction it 21 states that: (Reading) 22 Talc-containing powders may 23 promote cancer development through 24 local inflammation, increased rates of 25 cell division and DNA repair,</p>	<p style="text-align: right;">Page 241</p> <p>1 Q. I'm just going to ask you. Are you an 2 expert in animal studies? 3 A. No, I am not an expert in animal studies. 4 Q. In your opinion, in your -- strike that. 5 For purposes of your opinions in this 6 case, is it necessary that the ovaries be exposed to 7 talcum powder products, that they -- the product 8 itself reach the ovaries? 9 MR. FARIES: Objection to form. 10 THE WITNESS: As was described in this 11 paper, it is possible that exposure to talc 12 could create a generalized inflammatory 13 condition in the body that could contribute to 14 ovarian cancer. 15 BY MR. HEGARTY: 16 Q. Is it your opinion for purposes of this 17 case that inhalation of talcum powder products causes 18 ovarian cancer? 19 A. As I just stated, I believe, excuse me, 20 that inhalation of talc could lead to a generalized 21 increased level -- increased inflammatory environment 22 in the body that could contribute to the risk of 23 ovarian cancer. 24 Q. Let me ask it a little different way. Is 25 it your opinion to a reasonable degree of scientific</p>

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<p>1 certainty that inhaled talcum powder products cause 2 ovarian cancer? 3 A. I don't think that I can make -- state my 4 opinion clearly that that -- that route of exposure is 5 the only way -- if that was the only route of 6 exposure, that that would be a cause. I just don't 7 think that the evidence is strong enough. 8 Q. Looking at that same question a little bit 9 different, is it your opinion that inhalation as the 10 sole route of exposure to a reasonable degree of 11 scientific certainty increases the risk of ovarian 12 cancer? 13 MR. FARIES: Objection to form. 14 THE WITNESS: I do not think that we have 15 adequate data about inhalation as the sole route 16 of exposure. 17 BY MR. HEGARTY: 18 Q. Do you agree that if a woman does have 19 talcum powder products that reach the ovary, that it 20 doesn't mean that they will develop ovarian cancer? 21 A. Like with any risk factor, not all people 22 exposed to that risk factor will develop a cancer. 23 Q. Can cornstarch -- strike that. 24 Can cornstarch exposure to ovarian tissue 25 lead to inflammatory response?</p>	<p>1 A. Yes, I do agree to that. 2 Q. Not all chronic inflammatory conditions 3 increase the risk of cancer, correct? 4 MR. FARIES: Objection to form. 5 THE WITNESS: Again, I -- it's hard to 6 answer questions about "all chronic inflammatory 7 conditions." Certainly we do have evidence that 8 chronic inflammatory conditions can lead to 9 cancer. Whether all possible in the entire 10 universe do, I can't answer that question. 11 BY MR. HEGARTY: 12 Q. Rheumatoid arthritis is a chronic 13 inflammatory condition, correct? 14 A. Yes, it is. 15 Q. Does rheumatoid arthritis increase the 16 risk of any type of cancer? 17 MR. FARIES: Objection to form. 18 THE WITNESS: I have never specifically 19 looked at that question. 20 BY MR. HEGARTY: 21 Q. Can you cite for me any animal studies 22 that have shown inflammation in the face of exposure 23 to talcum powder products that have led then to 24 development of a cancer or a neoplasia? 25 A. Once again, you're asking me questions</p>
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<p>1 MR. FARIES: Objection to form. 2 THE WITNESS: I do not know the answer to 3 that. 4 BY MR. HEGARTY: 5 Q. How about titanium dioxide, does titanium 6 dioxide exposure to ovarian tissue cause an 7 inflammatory response? 8 MR. FARIES: Objection to form. 9 THE WITNESS: I don't know. 10 BY MR. HEGARTY: 11 Q. Have you done any kind of analysis to look 12 at whether other particles that can potentially reach 13 the ovary besides asbestos or talc cause an 14 inflammatory response that could lead to ovarian 15 cancer? 16 A. Please repeat that. 17 Q. Sure. Have you done any type of analysis 18 to look at whether other particles that could reach 19 the ovary besides asbestos or talcum powder products 20 could cause an inflammatory response that leads to 21 cancer? 22 A. I have not done that analysis again, 23 considering my area of expertise. 24 Q. You agree that not all inflammation in the 25 body leads to cancer, correct?</p>	<p>1 that are outside my area of expertise. 2 Q. So is the answer that you can't cite -- 3 A. I cannot -- 4 Q. -- any such studies? 5 A. I cannot cite them because -- for the 6 reasons stated. 7 Q. Are you aware of any study that has looked 8 at perineal exposure to talcum powder products and 9 then found those products in the ovaries of women? 10 MR. FARIES: Objection to form. 11 THE WITNESS: Yes, I have seen some of 12 those studies. 13 BY MR. HEGARTY: 14 Q. Can you cite for me any such study? 15 A. I believe that there's a study by 16 Henderson quite some time ago, and, again, off the top 17 of my head, can't remember the exact authors. 18 Q. Is it your memory that the authors in that 19 paper reported that the women who were studied applied 20 talcum powder to the perineal area? 21 A. I just can't -- you know, again, among the 22 hundreds of papers that I've read, I can't remember 23 those specific details. 24 Q. Can you cite for me any other paper where 25 you believe the authors have looked at women using</p>

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<p style="text-align: right;">Page 246</p> <p>1 talcum powder products and reported finding talcum 2 powder in their ovaries? 3 A. I'm sorry, how is that question different 4 than the one that I -- 5 Q. I asked you -- my question was whether you 6 can recall any other paper besides the Henderson paper 7 you mentioned. 8 A. I believe that there have been more than 9 one paper, but off the top of my head, I just can't 10 remember the author. 11 Q. With regard to the generation of reactive 12 oxygen species, a woman's monthly ovulatory process 13 causes inflammation that generates reactive oxygen 14 species, correct? 15 A. Yes, there is inflammation. 16 Q. So based on your theory, inflammation 17 resulting from monthly ovulation can cause reactive 18 oxygen species that can lead to cancer; is that 19 correct? 20 MR. FARIES: Objection to form. 21 THE WITNESS: As part of the overall 22 inflammation hypothesis, I think that the 23 evidence is pretty consistent showing that the 24 number of ovulatory cycles is related to a risk 25 of ovarian cancer.</p>	<p style="text-align: right;">Page 248</p> <p>1 oxygen and reactive nitrogen species every day, 2 correct? 3 A. Once again, I am not a cell biologist, but 4 that is my understanding. 5 Q. Even exercise would cause an increase in 6 the generation of reactive oxygen and nitrogen 7 species, correct? 8 A. Once again, you're getting somewhat out of 9 my area of expertise, but I think that that is my 10 understanding. 11 Q. Obesity is an inflammatory process, 12 correct? 13 A. Yes. 14 MR. FARIES: Objection to form. 15 BY MR. HEGARTY: 16 Q. Obesity would then cause an increase in 17 the generation of reactive oxygen and nitrogen 18 species, correct? 19 MR. FARIES: Objection to form. 20 THE WITNESS: Yes, that has been -- yes. 21 BY MR. HEGARTY: 22 Q. Are there particular studies -- strike 23 that. 24 What studies do you rely upon for purposes 25 of your Bradford Hill analysis as it relates to</p>
<p style="text-align: right;">Page 247</p> <p>1 BY MR. HEGARTY: 2 Q. And in a given woman using talcum powder 3 products, how can you distinguish between the effect 4 of ovulation versus the effect of using talcum powder 5 products? 6 MR. FARIES: Objection to form. 7 THE WITNESS: Okay. In our studies one of 8 the ways that we would do that is to control for 9 factors related to ovulation, such as the number 10 of pregnancies and periods of oral contraceptive 11 use and -- but when there are multiple exposures 12 from an epidemiologic study, it would be hard to 13 parse out which one. 14 BY MR. HEGARTY: 15 Q. You can only control if you -- in that 16 situation you described -- if you actually had the 17 total number of ovulatory cycles of the women in the 18 study, correct? 19 A. So you could use the factors that I 20 described as a reasonable proxy for the number of 21 ovulatory cycles, but it is a recognition that without 22 doing hormonal measurements on every woman, every 23 cycle, you could not absolutely calculate the number 24 of ovulatory cycles. 25 Q. The cells of our bodies produce reactive</p>	<p style="text-align: right;">Page 249</p> <p>1 biologic plausibility? 2 A. In my -- as I have said, not being a 3 cancer cell biologist, I have not gone back to 4 original studies talking about reactive oxygen 5 species. I have relied on articles that have more 6 generally discussed the role of inflammation in 7 cancer. 8 Q. Besides those studies, those studies -- 9 those articles that have discussed generally the role 10 of inflammation in cancer, are there any other 11 particular studies that you rely upon for your opinion 12 that the biologic plausibility factor under the 13 Bradford Hill criteria or guidelines supports a 14 finding of causality between talcum powder products 15 and ovarian cancer? 16 A. Again, I'm -- 17 Q. Well, you had given us one category of 18 studies. 19 A. Right. 20 Q. Are there any other categories of studies 21 that supports a finding of biologic plausibility under 22 the Bradford Hill guidelines for purposes of your 23 analysis in this case? 24 A. Okay. Once again, when I read multiple 25 papers that are describing the role of inflammation in</p>

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<p>1 cancer, I am relying on that. Going back to the 2 laboratory studies per se, I am not qualified to 3 evaluate how well they were done, and so I do rely on 4 these papers that are a summary of the evidence 5 related to inflammation in cancer. 6 Q. The reason I'm asking is because this is 7 our chance to find out what the papers are that you 8 rely upon under the biologic plausibility factor or 9 section of Bradford Hill. And we don't have the 10 report from you that lists those out, so I'm just 11 trying to itemize what those studies are. And is 12 there any other way, either your review of the 13 reliance materials that you can define for me the 14 studies that you refer to when you're talking about 15 the generalized papers on inflammation in cancer? 16 A. Once again, you know, I'm considering the 17 entire body of literature. To characterize a paper 18 as, That is the one that I relied on, I don't think 19 that's a reasonable way to characterize it. 20 Q. Well, you're not relying on the entire 21 body of literature for the biologic plausibility 22 factor under Bradford Hill, are you? 23 A. To some extent, yes, because many of the 24 papers that describe, like, an epidemiologic study, 25 they are also discussing the biologic plausibility.</p>	<p>1 tissues? 2 MR. FARIES: Objection to form. 3 THE WITNESS: No. In the epidemiologic 4 studies, we are -- the studies that considered a 5 dose response were the reported use of it. 6 There's no way to measure the dose to the ovary. 7 BY MR. HEGARTY: 8 Q. What studies, in your opinion -- or strike 9 that. 10 Is it your opinion that dose response has 11 been shown under the Bradford Hill criteria between 12 talcum powder use and ovarian cancer? 13 A. Okay. When considering the dose response 14 criteria, some studies reported on years of use, some 15 reported on frequency of use, and some reported on 16 some combination of frequency and duration of use. 17 The ones that consider only duration of use or only 18 frequency of use, we recognize that that is a 19 suboptimal way to assess dose response because some 20 women may use it very frequently but not for very 21 long, some women may use it for a very long time but 22 use it very sporadically. And so when considering it, 23 I looked primarily -- you know, I looked at all of the 24 studies, but I felt like the information derived from 25 the studies that reported on both -- some measure that</p>
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<p>1 Q. Are there any papers that you rely upon 2 under the biologic plausibility factor that look 3 specifically at or that tested whether inflammation is 4 a mechanism by which ovarian cancer occurs, not papers 5 that commented on what other papers have done, but the 6 underlying papers themselves, and not generally, but 7 specifically to ovarian cancer? 8 A. I don't recall reading any of those 9 specifically. 10 Q. One of the other criteria under Bradford 11 Hill is dose response. Did you consider dose response 12 for purpose of your opinions? 13 A. I did. 14 Q. You did not previously list that when I 15 asked you about the Bradford Hill criteria that you 16 reviewed. Why didn't you list that? 17 MR. FARIES: Objection to form. 18 THE WITNESS: There is a whole list of 19 criterion. As I indicated, I considered all of 20 them at the moment. That one did not come to 21 mind as I was trying to list that whole list. 22 BY MR. HEGARTY: 23 Q. In your analysis of dose response, did you 24 try to quantify the amount of talcum powder product 25 exposure for a given use, that is, exposure to the</p>	<p>1 combined frequency and duration, the majority of the 2 studies did, in fact, report a dose response. 3 Q. Cite for me the studies that looked at 4 duration and frequency that did report a statistically 5 significant dose response. 6 MR. FARIES: Objection to form. Are you 7 waiting on me? 8 THE WITNESS: Well, I didn't know if you 9 had more there. Okay. 10 MR. FARIES: Could we have the question 11 either reasked -- 12 MR. HEGARTY: Sure. 13 MR. FARIES: -- or ask the court reporter 14 to read it? 15 MR. HEGARTY: I'll restate it. 16 MR. FARIES: Okay. 17 BY MR. HEGARTY: 18 Q. Cite for me the studies that reported a 19 statistically significant dose response looking at 20 frequency and duration. 21 A. Okay. Some of our own study, first of 22 all, we came up with the estimated number of 23 applications, which was a combination of the frequency 24 and duration, and we did find statistically 25 significant associations for the genital use. The</p>

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<p>1 Terry study, which combined across eight case-control 2 studies, she also reported a statistically significant 3 dose response relation. And right off the top of my 4 head, it's just hard to pull up all of the studies, 5 but those are two that very definitely come to mind. 6 Q. Well, feel free, if you want to look at 7 your reliance materials, to refresh your memory. 8 MR. FARIES: I'll get that out. Just a 9 second. 10 (WITNESS REVIEWS DOCUMENT) 11 THE WITNESS: Yeah, once again, every 12 paper has multiple tables, and it is a little 13 bit difficult to remember off the top of my head 14 the whole list of studies that did find that 15 evidence of the dose response relation when 16 considering some measure of applications. 17 BY MR. HEGARTY: 18 Q. Well -- 19 A. You know, I want to be accurate in what 20 I'm stating, and sometimes with so many studies it's a 21 little bit difficult to remember which -- which found 22 that. And, I'm sorry, it's -- just with so many, it's 23 a little hard to recall all of them right off the top 24 of my head late in the day. 25 Q. Understood, but you -- do you understand</p>	<p>1 read to you about the studies that reported on a dose 2 response. Do you recall that -- 3 A. I do. 4 Q. -- that minor question? 5 A. Yes. 6 Q. Other than that part of the Schildkraut 7 paper, can you cite for me any other paper of yours 8 where you have made the statement that the studies 9 generally show a dose response or the majority of 10 studies show a dose response between talcum powder use 11 in ovarian cancer? 12 A. I don't believe that I have ever made that 13 statement in a published paper. 14 Q. You mentioned the Terry paper -- 15 A. Right. 16 Q. -- as showing a dose response, and I'll 17 mark as Exhibit 21 the Terry paper entitled Genital 18 Powder Use and Risk of Ovarian Cancer: A Pooled 19 Analysis of 8525 cases and 9859 Controls. 20 (EXHIBIT NUMBER 21 WAS MARKED FOR IDENTIFICATION) 21 BY MR. HEGARTY: 22 Q. Is this the Terry paper you referenced? 23 A. Yes. 24 Q. If you look at the abstract, on the first 25 page of that paper, about five lines up from the</p>
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<p>1 that this is our chance, in this setting, to find out 2 from you which studies that you contend are in this 3 majority of studies you said that show a statistically 4 significant association between frequency and duration 5 in ovarian cancer? 6 MR. FARIES: Objection to form. 7 BY MR. HEGARTY: 8 Q. And are you able to cite for me any other 9 studies besides your study, the Schildkraut study, and 10 the Terry study? 11 A. And, again, I believe that the study by 12 Anna Wu from -- and I also believe that some Cramer -- 13 at least one of the Cramer studies, one or more. And, 14 again, you know, off the top of my head, those are the 15 ones that are coming to mind. 16 Q. Do you recall from -- and feel free, 17 again, to look at your reliance materials -- what Anna 18 Wu study and what Cramer study by year, if you can, or 19 publication name or title. 20 A. I -- you know, I do not want to misstate 21 it, and I'm sorry, just from the title, I can't 22 remember which of the Wu studies specifically reported 23 on that and similarly with the Cramer study. 24 Q. And we looked a moment ago at the 2016 25 Schildkraut paper. We looked at a sentence that I</p>	<p>1 bottom the authors write: (Reading) 2 Among genital powder users, 3 we observed no significant trend in 4 risk with increasing number of 5 lifetime applications (assessed in 6 quartiles). 7 Did I read that correctly? 8 A. That is what it says in the abstract, yes. 9 Q. So what the Terry authors are reporting in 10 this part of the paper, is that they found no dose 11 response when looking at frequency times duration, 12 correct? 13 MR. FARIES: Objection to form. 14 THE WITNESS: Please repeat that. 15 BY MR. HEGARTY: 16 Q. So what the abstract reports -- well, 17 strike that. 18 So the abstract notes that the authors 19 found no dose response in looking at the number of 20 lifetime applications, which is duration times 21 frequency, correct? 22 A. That's what the abstract reports. And 23 within the paper, they report a -- Although a 24 significant increase in risk with an increasing number 25 of genital powder applications was found for</p>

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<p>1 nonmucinous epithelial ovarian cancer when nonusers 2 were included in the analysis, and reporting highly 3 significant P value for trend, they said no trend was 4 evident in analyses restricted to ever-users of 5 genital powder, and there is considerable discussion 6 about which is the most appropriate way to do that. 7 It's like clearly, the nonusers, that is often 8 included in calculation of trends. 9 Q. Is it your testimony that it's improper, 10 that it's not proper epidemiologic methods to include 11 only users of only exposed? 12 MR. FARIES: Objection to form. 13 BY MR. HEGARTY: 14 Q. Users or exposed? 15 A. I am not saying that it is improper. I'm 16 saying that it is done both ways in studies. 17 Q. And for purposes of this study, the 18 authors chose to report in the abstract the findings 19 as to -- as to when users were only included, correct? 20 A. That is what they reported in the 21 abstract. 22 Q. Have you ever done a study where you 23 looked at dose response only considering the exposed 24 and not using nonexposed for the calculation? 25 A. In a specific circumstance, yes.</p>	<p>1 there was -- I don't think that -- I'm trying to 2 remember the exact phrasing of the question. 3 Q. I think my question's a little bit 4 different. 5 A. Oh, yeah. 6 Q. For purposes of your opinions in this 7 case -- 8 A. Oh, for considering -- for the overall 9 opinions. I'm sorry. 10 Q. Correct, did you analyze the studies that 11 looked at talcum powder-covered diaphragms and talcum 12 powder-covered condoms? 13 A. I did not analyze but I considered studies 14 that reported on that. 15 Q. Can you explain to me the difference 16 between analyzing and considering? 17 A. When analyzing it, I did not do, for 18 example, a meta-analysis where -- actually did an 19 analysis of the data in that sense. 20 Q. Do you recall coming to any conclusions as 21 to what the papers showed looking at talc-dusted 22 diaphragms and talc-dusted condoms in relation to 23 ovarian cancer risk? 24 A. In relation to the diaphragms, there have 25 been several studies. Some found no association, some</p>
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<p>1 Q. What specific circumstance was that? 2 A. In some of the studies that have looked at 3 trying to understand both the effect of the number of 4 pregnancies as well as the timing of pregnancy, for 5 statistical reasons we base that analysis only on 6 women who had a pregnancy. 7 Q. Do you remember what paper that was? 8 A. That was a paper from the North Carolina 9 Ovarian Cancer Study. I was the first author, and it 10 was something related to comparison of characteristics 11 by -- I believe by menopausal status. Hormonal Risk 12 Factors for Ovarian Cancer in Pre- and Postmenopausal 13 Women. 14 Q. You mentioned a moment ago that looking at 15 dose by duration or looking at dose by frequency was a 16 suboptimal way to measure dose response, but you have 17 used that -- both of those methods in your papers, 18 correct? 19 A. Yes. Sometimes you have to. 20 Q. In forming your opinions in this case, did 21 you analyze the literature looking at ovarian -- I'm 22 sorry, looking at talcum powder exposure via condoms 23 or diaphragms? 24 A. The only analyses from our paper, I 25 believe they are all presented in this paper, and so</p>	<p>1 found an odds ratio greater than 1. None of them were 2 statistically significant increased risk. 3 Q. How about the studies looking at 4 talc-dusted condoms? 5 A. I know that that has been reported in some 6 papers. There -- to my knowledge, there has not been 7 a meta-analysis that combined all of that, and I 8 didn't -- did not consider that as a major factor. 9 MR. FARIES: We've been going for over an 10 hour, so before you get to the next -- 11 MR. HEGARTY: Okay. I'll just finish up 12 this section. 13 MR. FARIES: Okay. 14 BY MR. HEGARTY: 15 Q. Why did you not consider the talc-dusted 16 condoms studies to be a major factor? 17 A. Mostly because I felt like the amount of 18 data that was available was quite limited. 19 Q. Why wouldn't your analysis of the 20 talc-dusted diaphragm studies showing no overall 21 statistically significant association argue against 22 causation? 23 MR. FARIES: Objection to form. 24 THE WITNESS: I agree that that is a 25 somewhat surprising finding. I think that there</p>

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<p>1 might be reasons for that. The studies 2 typically looked at women who had that exposure 3 and no other talc exposure. I believe that's 4 how most of them reported on it. And so there 5 could be issues related to the frequency of use, 6 like, for example, women who used it only on a 7 diaphragm might have used it quite less 8 frequently than daily. Another consideration is 9 that when women use diaphragms, even if they 10 stored them in talc, they may have rinsed them 11 off, they should have used a spermicidal jelly 12 which might have interfered with any movement of 13 the particles up the genital track. So those 14 are potential reasons why those associations 15 weren't seen. 16 MR. HEGARTY: Okay. We can take that 17 break. 18 MR. FARIES: Yeah. 19 (RECESS TAKEN FROM 4:42 P.M. TO 4:58 P.M.) 20 BY MR. HEGARTY: 21 Q. All right. Dr. Moorman, we're back on the 22 record. 23 Do you agree that medical science has not 24 yet determined all the risk factors for ovarian 25 cancer?</p>	<p>1 relative risk, it's more a lifetime penetrance. 2 Q. Well, if you had a background rate of 1.4 3 percent and with a BRCA1 mutation your risk went up to 4 50 percent, wouldn't that be essentially about 30 to 5 40 times in terms of a relative risk or odds ratio? 6 MR. FARIES: Objection to form. 7 THE WITNESS: Yes, and again that's kind 8 of the upper end of the estimated penetrance of 9 that gene. 10 BY MR. HEGARTY: 11 Q. How about the lifetime risk of a woman who 12 has a BRCA2 genetic mutation? 13 A. Off the top of my head, I can't remember 14 the exact lifetime penetrance, but again, strong. I 15 believe it is not as strong as with BRCA1. 16 Q. It's a stronger -- it's a more strongly 17 associated risk factor than talcum powder exposure. 18 Do you agree with that? 19 MR. FARIES: Objection. 20 THE WITNESS: I do agree. 21 BY MR. HEGARTY: 22 Q. Do you consider BRCA1 -- a BRCA1 gene 23 mutation to be a cause of ovarian cancer? 24 A. Yes, I would consider it a cause. 25 Q. How about BRCA2 gene mutation, are -- is</p>
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<p>1 A. I think that that is very possible. 2 Q. Do you agree that being BRCA1 or BRCA2, 3 that's B-R-C-A-1 or B-R-C-A-2, is a risk factor for 4 ovarian cancer? 5 A. Yes, I do agree. 6 Q. In fact, I believe you stated in a paper 7 in the past that being BRCA positive is strongly 8 associated with ovarian cancer. Would that be a fair 9 statement? 10 MR. FARIES: Objection to form. 11 THE WITNESS: Yes, it is considered a 12 strong risk factor for ovarian cancer. 13 BY MR. HEGARTY: 14 Q. Do you know approximately what the 15 relative risk is for getting -- excuse me -- ovarian 16 cancer of being BRCA1? 17 A. In those, most studies report a range of 18 the -- the penetrance, so the lifetime risk of ovarian 19 cancer, the exact values are hard to come -- pull up 20 right off the top of my head. I want to say some have 21 a reported lifetime risk as high as 50 percent. 22 Q. And in terms of a relative risk or odds 23 ratio, would that be in the range of 30 to 40? 24 A. It is a -- a very strong relative risk. 25 As I said, I don't typically see it reported as a</p>	<p>1 that a gene mutation that causes ovarian cancer? 2 A. Yes. 3 Q. There are other gene mutations that have 4 been examined and linked to ovarian cancer risk; 5 correct? 6 A. That is correct. 7 Q. Do you consider any other gene mutation 8 linked to ovarian cancer to be a cause of ovarian 9 cancer? 10 A. Yes, I -- I think they are a cause. May I 11 also inject in here that they are not the sole cause, 12 that not all women with these mutations will develop 13 ovarian cancer. 14 Q. Can a BRCA1 gene mutation be the sole 15 cause of ovarian cancer? 16 MR. FARIES: Objection to form. 17 THE WITNESS: I think that this, again, 18 relies on our knowledge of the biological 19 process. 20 BY MR. HEGARTY: 21 Q. What is your answer to my question? 22 A. My answer to it is that I -- I am not 23 sure, again, because I am not a cancer biologist. 24 Q. You would have the same answer if I asked 25 the question about a BRCA2 mutation, correct?</p>

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<p style="text-align: right;">Page 266</p> <p>1 A. Yes, I would.</p> <p>2 Q. Or any gene mutation, correct?</p> <p>3 A. Yes.</p> <p>4 Q. Sitting here today, can you identify any</p> <p>5 other gene mutation that's been causal -- that you</p> <p>6 believe is causally related to ovarian cancer besides</p> <p>7 BRCA1 and BRCA2?</p> <p>8 A. Let's see. I believe that some of the</p> <p>9 mismatch repair mutations, the MSH. Again, I am not a</p> <p>10 geneticist, but those are also associated with</p> <p>11 increased risk as I understand it.</p> <p>12 Q. How about CHECK2, C-H-E-C-K-2 (sic)?</p> <p>13 A. I believe so. I -- again, I'm not as</p> <p>14 familiar with that literature.</p> <p>15 Q. Do you agree that medical science has not</p> <p>16 identified all gene mutations that may cause ovarian</p> <p>17 cancer?</p> <p>18 A. I think that that statement is likely</p> <p>19 true.</p> <p>20 Q. BRCA1 and BRCA2 mutations were discovered</p> <p>21 just about 20 years ago, correct?</p> <p>22 A. They -- yes, they were identified in the</p> <p>23 mid '90s.</p> <p>24 Q. But they certainly existed before we</p> <p>25 identified them, correct?</p>	<p style="text-align: right;">Page 268</p> <p>1 a possible cause of ovarian cancer.</p> <p>2 Q. Is it your opinion that being obese</p> <p>3 increases the risk of developing ovarian cancer?</p> <p>4 A. Yes, it is my opinion.</p> <p>5 Q. You've actually been an author on several</p> <p>6 papers looking at obesity in ovarian cancer, correct?</p> <p>7 A. That is correct.</p> <p>8 Q. In some of those papers you reported odds</p> <p>9 ratios of 3.2. That's statistically significant,</p> <p>10 correct?</p> <p>11 A. Can you, please, pull out the paper to</p> <p>12 which you are referring?</p> <p>13 Q. And I'm trying to move things along.</p> <p>14 A. Okay.</p> <p>15 Q. And I'll ask you the name -- I'll give you</p> <p>16 the name of paper --</p> <p>17 A. Okay.</p> <p>18 Q. -- and we can pull it out if you need to.</p> <p>19 A. Okay.</p> <p>20 Q. There's a paper I read by Hoyo, H-O-Y-O,</p> <p>21 in 2005 that showed an odds ratio of 3.2. Do you</p> <p>22 recall that paper?</p> <p>23 A. I recall the paper. It's very difficult</p> <p>24 to recall all of the specific numbers from a specific</p> <p>25 paper.</p>
<p style="text-align: right;">Page 267</p> <p>1 A. That is correct.</p> <p>2 Q. And is it your belief that there are other</p> <p>3 gene mutations that can cause ovarian cancer that</p> <p>4 science has not yet identified?</p> <p>5 MR. FARIES: Objection to form.</p> <p>6 THE WITNESS: I think that that is very</p> <p>7 likely.</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q. You've reported on obesity as a risk</p> <p>10 factor for ovarian cancer, correct?</p> <p>11 A. Yes.</p> <p>12 Q. Is it your opinion that obesity causes</p> <p>13 ovarian cancer?</p> <p>14 A. I believe that it is a risk factor and</p> <p>15 that there, again, is a plausible biological mechanism</p> <p>16 by which it could lead to it. And again, I think that</p> <p>17 it -- it would not be unreasonable to say that it is a</p> <p>18 cause.</p> <p>19 Q. Have you come to the opinion that obesity</p> <p>20 causes ovarian cancer?</p> <p>21 A. I have not reviewed the obesity literature</p> <p>22 in the same depth as I have reviewed the talc</p> <p>23 literature. I -- my knowledge of it is that it is a</p> <p>24 very frequently reported that there is a plausible</p> <p>25 biological mechanism and so I think that it is -- it's</p>	<p style="text-align: right;">Page 269</p> <p>1 Q. Let me ask it a different way.</p> <p>2 Do you recall in any of the papers in</p> <p>3 which you've been an author reporting the odds ratio</p> <p>4 relative risk between obesity and ovarian cancer to be</p> <p>5 higher than a 1.25 to 1.3 odds ratio that you've</p> <p>6 talked about here today with regard to talcum powder</p> <p>7 products in ovarian cancer?</p> <p>8 MR. FARIES: Objection to form.</p> <p>9 THE WITNESS: Okay. Again, it's -- I</p> <p>10 believe that, yes, we have sometimes reported</p> <p>11 that in some of the papers. Trying to recall</p> <p>12 the exact numbers from a specific paper is -- is</p> <p>13 challenging.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. Do you -- is it -- strike that.</p> <p>16 Is it your opinion that whole milk</p> <p>17 consumption and lactose intake causes ovarian cancer?</p> <p>18 A. I have not formed a strong opinion on</p> <p>19 that. It's -- I have not reviewed that literature in</p> <p>20 the same detail as I have the talc literature.</p> <p>21 Q. You mentioned you haven't "formed --</p> <p>22 formed a strong opinion," have you formed any opinion</p> <p>23 as to whether whole milk consumption and lactose</p> <p>24 intake causes ovarian cancer?</p> <p>25 MR. FARIES: Objection to form.</p>

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<p>1 THE WITNESS: I know that has been 2 reported in some papers. I, again, have just 3 not looked at the paper -- those -- that topic 4 in sufficient detail to really form an opinion. 5 BY MR. HEGARTY: 6 Q. That -- that finding of an increased risk 7 is actually reported in papers you have done, correct? 8 A. I believe that was one of the papers that 9 was reported and, again, we would not make a judgment 10 on any single paper, but more on the body of 11 literature. 12 Q. Is it your opinion that high glycemic load 13 increases the risk of ovarian cancer? 14 A. Once again, that's one of the papers that 15 came out of our group and I believe that we did report 16 that. 17 Q. But do you have the opinion that high 18 glycemic load causes ovarian cancer? 19 A. Once again, I have not reviewed the entire 20 body of literature related to that factor and I would 21 not make a judgment on without doing review of all of 22 the literature. 23 Q. Is it your opinion that incessant 24 ovulation, high ovulatory cycles, causes ovarian 25 cancer?</p>	<p>1 Q. Fair enough. 2 Do you -- do you consider an open question 3 of whether certain levels of smoking can cause serous 4 ovarian cancer? 5 A. Once again, one would make that conclusion 6 based on the entire body of literature and I think 7 that the body of literature is somewhat inconsistent 8 about smoking as a risk factor for ovarian cancer. 9 Q. Have you done a sufficient analysis to 10 draw a conclusion as to whether certain levels or 11 extents of smoking can cause ovarian cancer, in 12 particular serous ovarian cancer? 13 A. I have not done that analysis, no. 14 Q. Is it your opinion that hormone 15 replacement therapy use causes ovarian cancer? 16 A. It is my opinion that there is pretty 17 consistent evidence that certain types of hormone 18 replacement therapy are, indeed, associated with -- 19 with ovarian cancers. 20 Q. Is -- is it your opinion that certain 21 types of hormone replacement therapy are at the same 22 level of risk factor and cause as talcum powder 23 products in ovarian cancer? 24 MR. FARIES: Objection to form. 25 THE WITNESS: I believe that most studies</p>
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<p>1 A. That is a very consistently reported risk 2 factor, and I think that it -- again, it -- I would 3 feel comfortable saying that that was a potential 4 cause of ovarian cancer. 5 Q. Is your opinion the same as to incessant 6 ovulation as a cause of ovarian cancer as it is talcum 7 powder products as a cause of ovarian cancer? 8 MR. FARIES: Objection to form. 9 THE WITNESS: I think, yes, yes. 10 BY MR. HEGARTY: 11 Q. Is cigarette smoking, in your opinion, a 12 cause of ovarian cancer? 13 A. It is my opinion that the data are more -- 14 are fairly inconsistent about that and so, once again, 15 I have not formed that opinion. 16 Q. You recently did a study with Linda 17 Kelemen that reported in -- statistically significant 18 increased risk of certain levels of smoking in serous 19 ovarian cancer. Do you recall that? 20 A. I recall that paper, yes. 21 Q. That was a -- quite a note worthing 22 finding, wasn't it? 23 A. It was a finding from the paper, you know. 24 I don't know what you mean specifically by "note 25 worthy."</p>	<p>1 have reported a relative risk that is pretty 2 comparable to what we are seeing with with talc. 3 I believe that, you know, typically the odds 4 ratios are considerably below 2. 5 BY MR. HEGARTY: 6 Q. Have you formed an opinion as to hormone 7 replacement therapy of any level being causally 8 related to ovarian cancer in the same manner you have 9 done so in this case as to talcum powder products in 10 ovarian cancer? 11 MR. FARIES: Objection to form. 12 THE WITNESS: Okay. Once again, I have 13 read that literature. I have not done it 14 probably in the same detail that I have reviewed 15 the literature related to talc exposure. 16 BY MR. HEGARTY: 17 Q. So would it be a fair statement that you 18 don't have the same level of opinion or confidence in 19 your opinion for hormone replacement therapy as you do 20 for talcum powder? 21 A. As I said, I have not reviewed that 22 literature in the same level of detail so probably my 23 level of confidence about talc is -- is stronger. 24 Q. Same questions that I've been asking as to 25 endometriosis. Is it your opinion that endometriosis</p>

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<p>1 is a cause of ovarian cancer?</p> <p>2 A. Once again, I'll stipulate that all of</p> <p>3 these other risk factors, I have not reviewed the</p> <p>4 literature in quite the same detail that I have talc.</p> <p>5 However, I think that endometriosis is a pretty fairly</p> <p>6 consistently reported risk factor for ovarian cancer.</p> <p>7 Q. Do you have the opinion that endometriosis</p> <p>8 can cause ovarian cancer?</p> <p>9 A. Yes, I . . .</p> <p>10 Q. How about a first-degree family history of</p> <p>11 ovarian or breast cancer, do you consider that to be a</p> <p>12 cause of ovarian cancer?</p> <p>13 MR. FARIES: Objection to form.</p> <p>14 THE WITNESS: Once again, family history</p> <p>15 is a very consistently reported risk factor and</p> <p>16 so . . .</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. Is age considered to be a cause of ovarian</p> <p>19 cancer?</p> <p>20 A. Age is a risk factor for ovarian cancer.</p> <p>21 When you're looking at a factor like -- like that,</p> <p>22 does age cause it, I guess in the sense that as you</p> <p>23 age, you -- you are at increased risk, but I think</p> <p>24 that we consider age in a different way than we would</p> <p>25 consider some of these more exogenous exposures.</p>	<p>1 asbestos is one.</p> <p>2 Q. I should have you indicated that one --</p> <p>3 A. Okay.</p> <p>4 Q. -- in your list of opinions. And -- and</p> <p>5 you would include talcum powder exposure --</p> <p>6 A. Yes.</p> <p>7 Q. -- correct?</p> <p>8 A. Yes.</p> <p>9 Q. Anything else?</p> <p>10 A. You did not touch on pregnancy history, so</p> <p>11 nulliparity.</p> <p>12 Q. Do you consider nulliparity to be a cause</p> <p>13 of ovarian cancer?</p> <p>14 A. It is a uniformly reported risk factor for</p> <p>15 ovarian cancer so I think that it -- again, I'm trying</p> <p>16 to understand, you know, the parsing between cause and</p> <p>17 risk factors.</p> <p>18 Q. Well, you believe that talc is not only</p> <p>19 a -- talcum powder products are not only a risk factor</p> <p>20 but also a cause, correct?</p> <p>21 A. Right.</p> <p>22 Q. Which of the -- strike that.</p> <p>23 Which other risk factors --</p> <p>24 A. Okay.</p> <p>25 Q. -- is it your opinion are also a cause for</p>
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<p>1 Q. Is it your opinion that having Lynch</p> <p>2 syndrome cause -- can cause ovarian cancer?</p> <p>3 A. Yes.</p> <p>4 Q. Can infertility medications, in particular</p> <p>5 Clomid, in your opinion, cause ovarian cancer?</p> <p>6 A. My knowledge of that suggests that the</p> <p>7 data are somewhat inconsistent in relation to that.</p> <p>8 Q. Does -- is it your opinion -- or strike</p> <p>9 that.</p> <p>10 What is your opinion as to whether coffee</p> <p>11 is a risk factor for ovarian cancer, coffee intake?</p> <p>12 A. I don't have an opinion on that. I don't</p> <p>13 recall consistent body of literature related to that.</p> <p>14 Q. So far I've talked about, for purposes of</p> <p>15 risk factors, genetic mutation, obesity, whole milk</p> <p>16 consumption, high glycemic load, incessant ovulation,</p> <p>17 cigarette smoking, hormone replacement therapy, family</p> <p>18 history -- first-degree family of ovarian or breast</p> <p>19 cancer, endometriosis, and age and Lynch syndrome and</p> <p>20 Clomid exposure. If you can remember that list, going</p> <p>21 back -- I'll go back to more of a broad question.</p> <p>22 Other than what we've talked about, do you consider</p> <p>23 the evidence as established, in your opinion, any</p> <p>24 other risk factors that can cause ovarian cancer?</p> <p>25 A. As we have discussed previously today,</p>	<p>1 ovarian cancer?</p> <p>2 MR. FARIES: Objection to form.</p> <p>3 THE WITNESS: I --</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. Besides those we've talked about already.</p> <p>6 A. Right. Which -- which other ones?</p> <p>7 Q. That we have not discussed.</p> <p>8 A. That we have not discussed. Given that</p> <p>9 pretty exhaustive list, I think that we've -- I -- I</p> <p>10 can't think of anything off the top of my head that</p> <p>11 you have not mentioned.</p> <p>12 Q. Let me just give you a list of other</p> <p>13 things and then when I'm done you can tell me if any</p> <p>14 other --</p> <p>15 A. Okay.</p> <p>16 Q. -- of those qualify as both a risk factor</p> <p>17 and a cause, and wait until I finish. Diabetes, age</p> <p>18 at menarche, age at menopause, vitamin D deficiency,</p> <p>19 acrylamide use, caffeine use, Peutz-Jeghers syndrome,</p> <p>20 and I believe that's it.</p> <p>21 A. Okay. Among that list, I think those</p> <p>22 factors are less consistently associated with ovarian</p> <p>23 cancer. And I have to say you -- the acrylamide, and</p> <p>24 I am completely unfamiliar with that so I can't</p> <p>25 comment on that. The others, I think, are -- are less</p>

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<p>1 consistently associated with ovarian cancer and so I 2 would not describe them as a cause of ovarian cancer. 3 Q. Do you agree that medical science has not 4 identified all the causes of ovarian cancer? 5 A. I think that that is very possible. 6 Q. Can you identify anyone in the medical 7 community who has accepted talcum powder exposure as a 8 cause of ovarian cancer? 9 MR. FARIES: Objection to form. 10 THE WITNESS: Okay. I think that when you 11 consider the medical community broadly that 12 there are, indeed, people who have come out as 13 stating that. Dan Cramer, who has studied this 14 for many years, has. Jack Siemiatycki. Graham 15 Colditz has. So those are some examples. 16 BY MR. HEGARTY: 17 Q. Are you aware that all three of those 18 individuals are experts for Plaintiffs in the talc 19 litigation? 20 A. I am aware of that. 21 Q. Can you identify for me anyone in the 22 medical community who is not a retained expert for the 23 Plaintiffs who has accepted talc as a cause of ovarian 24 cancer? 25 A. I think that there are many people who</p>	<p>1 besides the three doctors you mentioned who believes 2 that talcum powder products cause ovarian cancer? 3 A. I don't know what people believe. I -- 4 again, I am relying on what they have written in the 5 literature saying that they consider it a risk factor. 6 Q. Going back just to a little bit of your 7 background. You are not an oncologist, correct? 8 A. No, I am not. 9 Q. You don't have expertise in cell biology, 10 correct? 11 A. No, I do not. 12 Q. You don't have expertise in pathology, 13 correct? 14 A. No, I do not. 15 Q. You are not a toxicologist, correct? 16 A. No, I am not. 17 Q. And over the course of your career, have 18 you ever been reprimanded or disciplined in any way? 19 A. No. 20 Q. Does your CV contain a complete list of 21 your publications, presentations, abstracts? 22 A. It contains a complete list of my 23 publications. The abstracts, I think those are 24 selected, so, for example, if I was listed as a 25 coauthor on an abstract at some meeting, I wouldn't</p>
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<p>1 have published on this who have described it as a risk 2 factor for ovarian cancer. I think that it is -- as a 3 whole, epidemiologists and people tend to be very 4 cautious about using the word "cause," and that I 5 think most people interpret risk factors and causes, 6 when there is a plausible biological mechanism, as 7 pretty synonymous terms. 8 Q. Well, my -- my question is very specific. 9 A. Yes. 10 Q. Can you identify any person in the medical 11 community besides retained experts for Plaintiffs who 12 have accepted talcum powder products as a cause of 13 ovarian cancer? 14 A. What do you mean -- 15 MR. FARIES: Objection to the form. 16 THE WITNESS: -- by "accepted." 17 BY MR. HEGARTY: 18 Q. Who -- who agree that talcum powder 19 products cause ovarian cancer? 20 A. Again, I -- I think that we rely on the 21 published literature and I think that there have been, 22 you know, numerous authors that have indicated that 23 talc does seem to be a risk factor for ovarian cancer. 24 Q. My question, though, concerns cause. Can 25 you cite for me anyone in the medical community</p>	<p>1 necessarily have included that in my CV. 2 Q. Over the course of your teaching career, 3 have you ever taught courses that examine the 4 literature looking at talcum powder exposure and 5 ovarian cancer? 6 A. I have you taught a cancer epidemiology 7 course, and at the time that I taught it, that course 8 was -- included lectures given by many different 9 people. I was the course coordinator it was taught 10 by. Many people gave lectures and I did not give the 11 lecture on ovarian cancer when I was teaching that 12 course. 13 Q. What percentage of your time do you spend 14 teaching students? 15 A. I spend about one-third of my time 16 teaching physician assistant students and then a 17 somewhat less defined amount of time like working with 18 students in other capacities such as mentoring medical 19 students, serving on committees like dissertation 20 committees so . . . 21 Q. What do you spend the rest of your 22 two-thirds of time doing? 23 A. I spend some of that time on research and 24 I also have some administrative responsibilities 25 within my department as clinical research unit</p>

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<p>1 director.</p> <p>2 Q. What percentage of that two-thirds rest of</p> <p>3 your time is spent on research?</p> <p>4 A. It's -- all in all, my effort is fairly</p> <p>5 evenly divided.</p> <p>6 Q. Have you ever before served as an expert</p> <p>7 witness in litigation?</p> <p>8 A. No, I have not.</p> <p>9 Q. Have you ever before given a deposition?</p> <p>10 A. No, I have not.</p> <p>11 Q. Have you ever before testified in a court</p> <p>12 of law?</p> <p>13 A. No, I have -- other than traffic court,</p> <p>14 no.</p> <p>15 Q. So the first -- this is the first time</p> <p>16 you've ever served as an expert witness in any</p> <p>17 context?</p> <p>18 A. That is correct.</p> <p>19 Q. You brought with you today the -- a copy</p> <p>20 of the Schildkraut paper; is that correct?</p> <p>21 A. I did.</p> <p>22 Q. Did you bring with you here today any</p> <p>23 other materials?</p> <p>24 A. Only the deposition -- what is it?</p> <p>25 Q. The deposition notice?</p>	<p>1 a copy of all the literature you reviewed, that is a</p> <p>2 hard copy of all the literature reviewed, for purposes</p> <p>3 of this case?</p> <p>4 A. I cannot say that I have hard copies. I</p> <p>5 have -- probably have copied -- hard copies, some</p> <p>6 electronic copies, and some things I might have looked</p> <p>7 at but never retained a copy of.</p> <p>8 Q. You've not reviewed any person's medical</p> <p>9 records for purposes of your analysis in this case; is</p> <p>10 that correct?</p> <p>11 A. No, I have not.</p> <p>12 Q. If you look over on page 3 and 4 of</p> <p>13 Exhibit 22, there are a number of paragraphs marked</p> <p>14 1 through 11. Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. You brought with you your curriculum</p> <p>17 vitae, correct?</p> <p>18 A. I did.</p> <p>19 Q. Do you have any of the other materials</p> <p>20 that are listed in paragraphs 2 through 11 that are</p> <p>21 not also referenced on your disclosure document?</p> <p>22 A. I do not have any of these other</p> <p>23 documents. Okay.</p> <p>24 Q. In terms of your preparation to testify</p> <p>25 here today, did you review any documents to prepare to</p>
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<p>1 A. Notice, that's the word.</p> <p>2 Q. I'm marking as Exhibit Number 22 the</p> <p>3 deposition notice.</p> <p>4 A. Yes.</p> <p>5 (EXHIBIT NUMBER 22 WAS MARKED FOR IDENTIFICATION)</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q. Is that the same notice that you have</p> <p>8 brought with you here today?</p> <p>9 (WITNESS REVIEWS DOCUMENT)</p> <p>10 A. Yes, appears to be.</p> <p>11 Q. With regard to your work on this case,</p> <p>12 have you prepared any notes yourself where you sat</p> <p>13 down and -- and summarized studies or even made notes</p> <p>14 on written -- or on hard copies of studies?</p> <p>15 A. In -- for preparation for this case, no.</p> <p>16 Q. For preparation of this case, have you</p> <p>17 created any report, any outline, anything that sets</p> <p>18 out all or part of your opinions in this case?</p> <p>19 A. No, I have not.</p> <p>20 Q. And in terms of reviewing articles, did</p> <p>21 you ever for purpose of this case review articles and</p> <p>22 write notes or comments on the articles themselves?</p> <p>23 A. I do not typically do that. I don't</p> <p>24 recall doing that.</p> <p>25 Q. Do you have back in your office or at home</p>	<p>1 testify here today?</p> <p>2 A. So reviewing documents such as papers?</p> <p>3 Q. Or anything. Medical literature,</p> <p>4 textbooks, anything of that nature?</p> <p>5 A. Yes, I -- you know, I -- we've given you</p> <p>6 the -- the reliance list and so all of this.</p> <p>7 Q. Let me ask it in a different way.</p> <p>8 Specifically for purposes of coming here</p> <p>9 today, not for developing your overall opinions but to</p> <p>10 prepare for this deposition, in the last couple days</p> <p>11 have you reviewed any articles or documents?</p> <p>12 A. Yes.</p> <p>13 Q. Which ones did you review?</p> <p>14 A. Within the last couple of days, I reviewed</p> <p>15 the Schildkraut paper. I also reviewed the -- a</p> <p>16 couple of documents that Mr. Faries gave to me related</p> <p>17 to some of the testing of powders for asbestos.</p> <p>18 Q. Those are documents that you had included</p> <p>19 on the list of reliance materials under company</p> <p>20 documents?</p> <p>21 A. Yes.</p> <p>22 Q. Do you recall which ones those were?</p> <p>23 A. These list -- the last three listed here,</p> <p>24 the William E. Long reports.</p> <p>25 Q. Okay. Any other documents you viewed in</p>

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<p>1 the last couple days for purposes of coming here today</p> <p>2 to testify?</p> <p>3 A. I looked at some other articles, for</p> <p>4 example, just refreshing my memory.</p> <p>5 Q. Do you remember which ones those were?</p> <p>6 A. Let's me see. One of them that I recall</p> <p>7 looking at specifically was the Gonzalez study from</p> <p>8 the Sister Study. There may have been others that</p> <p>9 were on this list that I might have looked at.</p> <p>10 Q. Sitting here right at this moment, do you</p> <p>11 recall any other studies having looked at in the last</p> <p>12 couple days besides those you've already told us</p> <p>13 about?</p> <p>14 A. In the last couple of days, I -- I don't</p> <p>15 recall.</p> <p>16 Q. You mentioned -- I'm sorry.</p> <p>17 A. Go ahead.</p> <p>18 Q. Were you finished?</p> <p>19 Well, you mentioned that you thought you</p> <p>20 had spent 50 hours in preparation -- in developing</p> <p>21 your opinions in this case. Is that a fair estimate?</p> <p>22 A. Yes.</p> <p>23 Q. Are you able to estimate how much of that</p> <p>24 time was spent reviewing medical literature?</p> <p>25 A. I would say that probably 30 to 40 hours</p>	<p>1 Q. In terms of your communications with</p> <p>2 counsel for Plaintiffs, without identifying any of the</p> <p>3 nature of the communications, can you tell me how many</p> <p>4 times that you have spoken with counsel for Plaintiffs</p> <p>5 for purposes of developing your opinions or getting</p> <p>6 prepared to testify here today, just simply the number</p> <p>7 of times?</p> <p>8 A. How many -- how many times? I would say</p> <p>9 probably about half a dozen times.</p> <p>10 Q. Are you able to estimate in those half a</p> <p>11 dozen times how much time you spent in those</p> <p>12 communications?</p> <p>13 A. Probably 12 hours or so.</p> <p>14 Q. And in those communications, again without</p> <p>15 identifying any of the substance of those</p> <p>16 communications or anything that you were shown or</p> <p>17 looked at with counsel, can you identify who those</p> <p>18 meetings were with, what attorneys? I assume one was</p> <p>19 Mr. Faries; is that correct?</p> <p>20 A. That is correct.</p> <p>21 Q. And also Mr. Gibson and Ms. Parfitt are</p> <p>22 here today. Did those meetings include those two</p> <p>23 attorneys?</p> <p>24 A. Some of them did.</p> <p>25 Q. Any other attorneys -- were any other</p>
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<p>1 of that.</p> <p>2 Q. Other than counsel for Plaintiffs in this</p> <p>3 case, did you speak with anyone in preparation for</p> <p>4 your deposition in this case about your deposition?</p> <p>5 A. Other than counsel for Plaintiffs?</p> <p>6 Q. Yes.</p> <p>7 A. No, I did not.</p> <p>8 Q. Have you ever spoken to any person besides</p> <p>9 counsel for Plaintiffs regarding your work here as an</p> <p>10 expert witness?</p> <p>11 A. No, I have not.</p> <p>12 Q. If you would look at your -- the</p> <p>13 disclosure of expert exhibit?</p> <p>14 MR. FARIES: Oh, I don't -- hang on, let</p> <p>15 me dig it out.</p> <p>16 MR. HEGARTY: Exhibit 1.</p> <p>17 MR. FARIES: Here it is. Oops.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. Would you look at that exhibit, Exhibit 1,</p> <p>20 and tell me whether you have spoken with any of the</p> <p>21 other doctors listed on the pages of expert</p> <p>22 disclosures in that document regarding your testimony</p> <p>23 or work on this case?</p> <p>24 A. No, I have not spoken to any of these</p> <p>25 people.</p>	<p>1 attorneys involved in the work you've done on the</p> <p>2 Ingham case besides those I've just identified?</p> <p>3 A. Yes, Dr. Bob Leone.</p> <p>4 Q. Okay. Anybody else?</p> <p>5 A. And another attorney, the first name is</p> <p>6 Jane and the last name is escaping me.</p> <p>7 Q. Okay. Anybody else?</p> <p>8 A. Oh. And in one of the meetings</p> <p>9 Mr. Faries' associate, Lee Cirsch was there.</p> <p>10 Q. Okay. Is that the list of attorneys you</p> <p>11 can recall?</p> <p>12 A. Yes.</p> <p>13 MR. HEGARTY: I would like the opportunity</p> <p>14 to review my notes while Mr. Klatt is asking</p> <p>15 questions, if that would be okay.</p> <p>16 MR. FARIES: Of course.</p> <p>17 MR. HEGARTY: As opposed to taking time</p> <p>18 off now.</p> <p>19 MR. FARIES: Yeah.</p> <p>20 MR. HEGARTY: And then when he's finished,</p> <p>21 finish up whatever else I can find that I</p> <p>22 haven't covered in my notes. Is that okay?</p> <p>23 MR. FARIES: It's okay.</p> <p>24 MR. HEGARTY: Okay. Thank you.</p> <p>25 MR. KLATT: Are you all ready to go</p>

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<p>1 forward?</p> <p>2 MR. HEGARTY: Yeah, let's do it.</p> <p>3 MR. KLATT: Okay.</p> <p>4 EXAMINATION</p> <p>5 BY MR. KLATT:</p> <p>6 Q. Good afternoon, Dr. Moorman. I'm Mike</p> <p>7 Klatt and I represent the company Imerys Talc America</p> <p>8 in this case. Have you ever heard of Imerys Talc</p> <p>9 America before this lawsuit?</p> <p>10 A. Before this lawsuit, no.</p> <p>11 Q. Do you -- do you understand what Imerys</p> <p>12 Talc America's role is here?</p> <p>13 A. I -- my understanding is that they provide</p> <p>14 material to Johnson & Johnson.</p> <p>15 Q. And when you say "material," what</p> <p>16 material?</p> <p>17 A. For talc products.</p> <p>18 Q. Is it your understanding that Imerys Talc</p> <p>19 Americas supplies the raw talc to Johnson & Johnson</p> <p>20 for their talc-based body powder products?</p> <p>21 A. This is my understanding.</p> <p>22 Q. Without getting into what you talked about</p> <p>23 with any attorneys, can you tell us to the best of</p> <p>24 your recollection the first date you were contacted by</p> <p>25 an attorney regarding the talc/ovarian cancer issue?</p>	<p>1 on talcum powder product and whatever they may</p> <p>2 contain.</p> <p>3 BY MR. KLATT:</p> <p>4 Q. But do you have any specific -- you've</p> <p>5 talked about talcum powder today and you talked about</p> <p>6 asbestos. Do you have any opinions on any other</p> <p>7 components or constituents of talc other than those</p> <p>8 two that may be in talc-based body powder products?</p> <p>9 A. Again, I'm talking about the overall</p> <p>10 product. I am aware that there may be other</p> <p>11 constituents in there and my opinion, again, is based</p> <p>12 on the overall talcum powder product.</p> <p>13 Q. Do you -- you've expressed specific</p> <p>14 opinions about asbestos --</p> <p>15 A. Asbestos.</p> <p>16 MR. FARIES: Hang on.</p> <p>17 THE WITNESS: Okay.</p> <p>18 MR. FARIES: Just slow down.</p> <p>19 THE WITNESS: Okay.</p> <p>20 MR. FARIES: Let him get his whole</p> <p>21 question out.</p> <p>22 THE WITNESS: Okay.</p> <p>23 BY MR. KLATT:</p> <p>24 Q. You've expressed opinions today about</p> <p>25 trace asbestos that may or may not be in talc, but</p>
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<p>1 A. It was related to this case?</p> <p>2 Q. By any attorney contacting you about talc</p> <p>3 and ovarian cancer issue?</p> <p>4 A. It was approximately summer of 2016.</p> <p>5 Q. And again without disclosing that</p> <p>6 attorney's identity unless they've already been</p> <p>7 discussed today, was that attorney who contacted you</p> <p>8 in the summer of 2016 one of the attorneys you've</p> <p>9 already mentioned here today?</p> <p>10 A. Yes.</p> <p>11 Q. And who was that?</p> <p>12 A. It was Jeff Gibson.</p> <p>13 Q. And I'm sorry, I'm skipping around.</p> <p>14 A. Okay.</p> <p>15 Q. I'm not going to go back through every</p> <p>16 single thing --</p> <p>17 A. Okay.</p> <p>18 Q. -- so if you'll be patient with me, I'm</p> <p>19 going to jump around.</p> <p>20 A. Okay.</p> <p>21 Q. Do you intend to express any opinions in</p> <p>22 this case on the subject of any trace metals that may</p> <p>23 or may not be in talc-based body powder products?</p> <p>24 MR. FARIES: Objection to form.</p> <p>25 THE WITNESS: Okay. My opinion is based</p>	<p>1 you've given opinions about that. Do you have any</p> <p>2 opinions like that about any other components of</p> <p>3 talc-based body powder products?</p> <p>4 A. I have not formulated opinions about other</p> <p>5 constituents.</p> <p>6 Q. Have you formed any opinion that</p> <p>7 talc-based body powder products cause breast cancer?</p> <p>8 A. I have not formed an opinion about that,</p> <p>9 no.</p> <p>10 Q. Have you formed any opinion that</p> <p>11 talc-based body powder products cause kidney cancer?</p> <p>12 A. I have not formed an opinion about that.</p> <p>13 Q. What about bladder cancer?</p> <p>14 A. No, I have not formed an opinion.</p> <p>15 Q. Have you formed any opinion that</p> <p>16 talc-based body powder products can cause vulvar</p> <p>17 cancer in women?</p> <p>18 A. I have not formed an opinion about that.</p> <p>19 Q. And are you aware of the type of cancer</p> <p>20 called vulvar cancer?</p> <p>21 A. Yes.</p> <p>22 Q. And that's the cancer that can form in the</p> <p>23 external genital area of women; is that correct?</p> <p>24 A. That is correct.</p> <p>25 Q. Do you have an opinion about talc-based</p>

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<p>1 body powder products causing vaginal cancer?</p> <p>2 A. I have not -- I do not have an opinion</p> <p>3 about that.</p> <p>4 Q. Do you have an opinion about talc-based</p> <p>5 body powder products causing cervical cancer?</p> <p>6 A. I do not have an opinion about that.</p> <p>7 Q. Do you have an opinion about talc-based</p> <p>8 body powder products causing uterine cancer?</p> <p>9 A. I do not have an opinion about that.</p> <p>10 Q. And uterine cancer is also called</p> <p>11 endometrial cancer; is that correct?</p> <p>12 A. That is correct.</p> <p>13 Q. Do you have any opinion about talc-based</p> <p>14 body powder products causing fallopian tube cancer?</p> <p>15 MR. FARIES: Objection to form.</p> <p>16 THE WITNESS: My opinion about that is</p> <p>17 kind of wrapped up in my opinion about ovarian</p> <p>18 cancer because it is becoming very -- it's been</p> <p>19 reported that some ovarian cancers originate in</p> <p>20 the fallopian tubes and so it is often very</p> <p>21 difficult to make a distinction about ovarian</p> <p>22 versus fallopian tube, and they are often</p> <p>23 considered all together.</p> <p>24 BY MR. KLATT:</p> <p>25 Q. Are you aware of any studies that have</p>	<p>1 am aware of some publications specifically</p> <p>2 related to endometrial cancer and talc.</p> <p>3 BY MR. KLATT:</p> <p>4 Q. And -- and none of those publications show</p> <p>5 an overall increased risk of endometrial or uterine</p> <p>6 cancer in women who used talc-based body powder</p> <p>7 products, correct?</p> <p>8 A. Once again, I have looked at them and the</p> <p>9 over -- my impression overall is that they are not</p> <p>10 showing increased risk. However, again, recalling</p> <p>11 whether or -- you know, the overall body of</p> <p>12 literature, which is limited, I don't see increased</p> <p>13 risk, but I can't recall if there were any</p> <p>14 statistically significantly increased risks reported.</p> <p>15 Q. Okay. Setting aside ovarian cancer and</p> <p>16 setting aside endometrial or uterine cancer, for any</p> <p>17 of these other types of cancers I've mentioned since</p> <p>18 I've been asking you questions the last few minutes,</p> <p>19 are you aware of any data at all showing an increased</p> <p>20 risk of any of those types of cancer associated with</p> <p>21 talc-based body powder product use in women?</p> <p>22 MR. FARIES: Objection to form.</p> <p>23 THE WITNESS: I am not aware of literature</p> <p>24 showing increased risk for those cancers,</p> <p>25 but . . .</p>
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<p>1 looked specifically at fallopian tube cancer and</p> <p>2 whether or not it's related to use of talc-based body</p> <p>3 powders in the genital area?</p> <p>4 A. I am not aware of any study that looked at</p> <p>5 fallopian tube cancer all on its own.</p> <p>6 Q. With respect to use of talc-based --</p> <p>7 A. Exactly.</p> <p>8 Q. -- body powder products?</p> <p>9 A. That's correct.</p> <p>10 Q. What about rectal or colorectal cancer?</p> <p>11 Are you aware of any studies -- or do you have an</p> <p>12 opinion whether use of talc-based body powder products</p> <p>13 in the genital area or elsewhere can cause rectal</p> <p>14 cancer or colorectal cancer?</p> <p>15 A. I have not formed an opinion about that</p> <p>16 for the same reason that I haven't formed an opinion</p> <p>17 about the other cancers that you've listed. I have</p> <p>18 not reviewed the literature in detail about it, and my</p> <p>19 impression is that the literature on other cancer</p> <p>20 sites is very limited.</p> <p>21 Q. Are you aware of any data at all on the</p> <p>22 use of talc-based body powder products and these other</p> <p>23 cancers other than ovarian cancer?</p> <p>24 MR. FARIES: Objection to form.</p> <p>25 THE WITNESS: Am I aware of any data? I</p>	<p>1 BY MR. KLATT:</p> <p>2 Q. And you agree with me, Dr. Moorman, that</p> <p>3 when a woman applies talc in the genital or perineal</p> <p>4 area that talc -- her rectal area could be exposed to</p> <p>5 talc, correct?</p> <p>6 A. Yes, that is possible.</p> <p>7 Q. Because it's in the same proximity as the</p> <p>8 reproductive tract --</p> <p>9 A. That is --</p> <p>10 Q. -- is that right?</p> <p>11 A. -- that is correct.</p> <p>12 Q. But you've seen no data at all that use of</p> <p>13 talc in the genital area increases the risk of rectal</p> <p>14 cancer; is that right?</p> <p>15 MR. FARIES: Objection to form.</p> <p>16 THE WITNESS: No, I do not recall any</p> <p>17 papers reporting that.</p> <p>18 BY MR. KLATT:</p> <p>19 Q. Now, let's talk for a second about your</p> <p>20 opinions about asbestos being related to ovarian</p> <p>21 cancer, okay?</p> <p>22 A. Uh-huh.</p> <p>23 Q. Those studies are all either, I think you</p> <p>24 said, occupational studies of women who worked in</p> <p>25 industries that had high asbestos exposure or</p>

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<p>1 environmental studies where women lived in the homes 2 where they had workers who worked in the asbestos 3 industry and brought it home; is that correct? 4 A. That is correct. 5 Q. And most of these studies are based on an 6 identification of ovarian cancer based on death 7 certificates, correct? 8 MR. FARIES: Objection to form. 9 THE WITNESS: Yes, many of them are 10 reporting on standardized mortality ratios. 11 BY MR. KLATT: 12 Q. And you'd agree that death certificates in 13 the epidemiologic community are a notoriously 14 unreliable way to determine actual diagnoses, correct? 15 MR. FARIES: Objection to form. 16 THE WITNESS: It is recognized that there 17 are some inaccuracies in death certificates. I 18 would not necessarily go so strong as to say 19 "notoriously unreliable." 20 BY MR. KLATT: 21 Q. How about just unreliable? 22 MR. FARIES: Objection to form. 23 THE WITNESS: I would, once again, say 24 there are some inaccuracies. I would not go so 25 far as to say "unreliable."</p>	<p>1 BY MR. KLATT: 2 Q. But in reviewing the literature on an 3 association between asbestos exposure and ovarian 4 cancer, you've undoubtedly seen that until the late 5 1990s pathologists didn't even have the ability to 6 distinguish between ovarian cancer and mesothelioma, 7 correct? 8 MR. FARIES: Objection to form. 9 THE WITNESS: I -- I can't recall reading 10 that and, again, I'm not pathologist. I do not 11 have firsthand knowledge. 12 BY MR. KLATT: 13 Q. Have you ever consulted with any sort of 14 company, pharmaceutical company, medical company, 15 consumer products company? 16 A. No, I have not. 17 Q. Do you think there's anything inherently 18 wrong with an epidemiologist or a scientist being 19 consulted on the outside by a company if they want to 20 get an outside opinion on a medical or scientific 21 issue? 22 A. I do not think that there is anything 23 "inherently wrong" with that. 24 Q. In fact, if you felt like companies needed 25 to access outside expertise of people like</p>
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<p>1 BY MR. KLATT: 2 Q. Well, you'd agree with me that when 3 someone signs a death certificate, whoever signs that 4 death certificate and states the cause of death, may 5 not even be the physician who was treating the person, 6 correct? 7 A. In truth, I have not been -- I'm not a 8 medical doctor so I have never been around when 9 someone has signed a death certificate. I have heard 10 that sometimes that happens, but I have not witnessed 11 it. 12 Q. As an epidemiologist, have you heard, 13 though, that death certificates can be an unreliable 14 source of accurate diagnosis? 15 A. Again, I would characterize it as they 16 can -- there can be inaccuracies in them. 17 Q. Are you aware that in terms of the 18 pathological tests that could be applied to 19 distinguish whether a cancer is ovarian cancer versus 20 a mesothelioma, are you aware those tests weren't even 21 developed until the late 1990s? 22 MR. FARIES: Objection to form. 23 THE WITNESS: Once again, I am not a 24 pathologist and I do not have the familiarity 25 with the tests that you are referring to.</p>	<p>1 epidemiologists or other types of scientists, it would 2 be perfectly acceptable to go out and contact them and 3 consult with them, correct? 4 A. Yes, I think that within the academic 5 community many people consult for -- for companies. 6 Q. And -- 7 A. I think it is appropriate. 8 Q. -- and as far as you know, those people do 9 the best they can in trying to give an objective 10 assessment of whatever issue they're asked to 11 evaluate, correct? 12 MR. FARIES: Objection to form. 13 THE WITNESS: Again, you're making a 14 very -- asking me to make an assessment about 15 thousands of people, and I don't know. I can't 16 speak for all of them. I think that there are 17 many people who are doing their best to do it. 18 Some maybe not. 19 BY MR. KLATT: 20 Q. Let's -- let's be more specific because 21 you have a fair point. Let's talk about your 22 colleagues at Duke. You have colleagues at Duke that 23 are asked to consult for industry on occasion, 24 correct? 25 A. Yes, I do.</p>

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<p>1 Q. And as far as you know, your colleagues at 2 Duke that are asked to consult for industry do their 3 best to give honest objective scientific and medical 4 opinions to the people they're consulting with, 5 correct? 6 MR. FARIES: Objection to form. 7 THE WITNESS: Again, you know, I think 8 that as a generalization, I would say that is 9 true, but again, we're still talking about many, 10 many people who might consult for industry. 11 BY MR. KLATT: 12 Q. Do you think -- do you have somebody 13 specific in mind at Duke who isn't giving their best 14 objective medical or scientific opinion when they're 15 consulting with industry on the outside? 16 A. I am not aware of anyone, but again, you 17 asked about a very large group of people. 18 Q. You said in response to Mr. Hegarty's 19 questions earlier that something has to cause ovarian 20 cancer, correct? Didn't you -- I mean, you said at 21 some level something has to be causing ovarian cancer 22 even if we don't know the specific risk factors in a 23 patient, correct? 24 MR. FARIES: Objection to form. 25 THE WITNESS: Okay. So, yes, something</p>	<p>1 events that -- along the pathway from a normal 2 cell to a transformed cancer cell and I don't 3 think that we have the knowledge to say that -- 4 in most situations I don't think we have the 5 knowledge to say that a single factor is the 6 single cause of that cancer. 7 BY MR. KLATT: 8 Q. But you would agree with me things like 9 smoking and radiation exposure are known causes of 10 cancer, correct? 11 A. I would agree with -- 12 Q. And -- 13 A. Yes. 14 Q. -- and the carcinogens in cigarettes or 15 the DNA-damaging properties of radiation are 16 sufficient in and of themselves to cause cancer, 17 correct? 18 MR. FARIES: Objection to form. 19 THE WITNESS: I would not agree with that 20 statement because if -- the way that I would 21 interpret that is that the DNA damage is 22 sufficient to cause the cancer, then it seems 23 you would be making the leap that everyone who 24 was exposed to that should develop cancer and we 25 know that that is not the case.</p>
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<p>1 causes the transformation from normal cells to 2 cancer cells. 3 BY MR. KLATT: 4 Q. And cancer, generally, and ovarian cancer, 5 specifically, is the result of mutations to the DNA in 6 cells that makes them behave abnormally, correct? 7 A. All cancers are thought to be a result of 8 DNA damage of some kind. 9 Q. And the DNA damage that starts a cancer in 10 a given person can be from a specific cause, correct? 11 MR. FARIES: Objection to form. 12 BY MR. KLATT: 13 Q. For example, in lung cancer, smoking can 14 be the cause of the original mutations that start the 15 cancer, correct? 16 MR. FARIES: Objection to form. 17 THE WITNESS: Yes, it's . . . 18 BY MR. KLATT: 19 Q. So there can be a single cause of a 20 cancer, correct, you don't always have to have 21 multiple causes? 22 MR. FARIES: Objection to form. 23 THE WITNESS: I -- again, going back to my 24 viewpoint that I am not a cancer biologist, it 25 is thought that in most cases there are multiple</p>	<p>1 BY MR. KLATT: 2 Q. Well, there's nothing, there's nothing out 3 there in the world that causes cancer in every person 4 exposed to it, correct? 5 A. None that I know of. 6 Q. But, for example, smoking doesn't cause 7 cancer in every single person that smokes, right? 8 A. That is correct. 9 Q. But you believe smoking causes cancer, 10 correct? 11 A. I believe that it can cause cancer. 12 Q. And radiation doesn't cause cancer in 13 everybody that gets an x-ray or gets a sunburn, but 14 you would agree with me that radiation is a cause of 15 cancer, correct? 16 A. I would agree that radiation can cause 17 cancer. 18 Q. What's the typical age range for diagnosis 19 of ovarian cancer? 20 MR. FARIES: Objection to form. 21 THE WITNESS: The median age of diagnosis 22 is approximately 60 years old. 23 BY MR. KLATT: 24 Q. And "median" means half the cases of 25 ovarian cancer are diagnosed in women older than 60</p>

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<p>1 and half the cases of ovarian cancer are diagnosed in 2 women younger than 60; is that right? 3 A. Yes, that's the definition of median age. 4 Q. Would you -- 5 MR. FARIES: I want you to slow down. 6 THE WITNESS: Okay. 7 MR. FARIES: After his finishes his 8 question, let there be a pause so I have a 9 chance to think and object -- 10 THE WITNESS: Okay. 11 MR. FARIES: -- and then you can answer. 12 Okay? 13 THE WITNESS: Okay. 14 MR. FARIES: I know you want to get 15 wrapped up, but let's just keep it -- 16 THE WITNESS: Okay. 17 MR. FARIES: -- going. 18 BY MR. KLATT: 19 Q. Do you agree, Dr. Moorman, that if a woman 20 is diagnosed with ovarian cancer in her 30s or 40s, 21 that's suggestive of an inherited genetic mutation 22 like BRCA or some family predisposition to cancer? 23 MR. FARIES: Objection to form. 24 THE WITNESS: I would agree that women who 25 are diagnosed at a younger age may be more</p>	<p>1 doctor, but that is my understanding. 2 BY MR. KLATT: 3 Q. Have you ever given a woman an opinion 4 that if she has a BRCA1 or BRCA2 mutation but has not 5 yet been diagnosed with ovarian cancer that she should 6 consider having her ovaries and fallopian tubes 7 removed? 8 A. No, I have not. 9 Q. So you don't ever counsel women, even 10 informally friends or family, about that; is that 11 correct? 12 MR. FARIES: Objection to form. 13 THE WITNESS: No, that is a discussion 14 with a medical professional, not -- a medical 15 doctor. 16 BY MR. KLATT: 17 Q. Have you seen any data that use of 18 talc-based body powders by women who have BRCA1 or 19 BRCA2 mutations increases their risk above and beyond 20 what it is already from having the BRCA1 or BRCA2 21 mutations? 22 A. I have not -- I am not familiar with any 23 data that has reported on that specifically. 24 Q. So you can't say use of talc body powder 25 by a woman with a BRCA mutation poses a special risk</p>
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<p>1 likely to have these genetic mutation, but I 2 would not say that all women diagnosed at a 3 younger age that it is suggestive that they have 4 a genetic mutation. 5 BY MR. KLATT: 6 Q. And -- and these genetic mutations that 7 we're talking about like BRCA1 and BRCA2 are inherited 8 either through the mother's family line or the 9 father's family line, correct? 10 A. That is correct. 11 Q. And we're increasingly realizing that 12 women can have these inherited mutations without 13 having a family history of cancer, correct? 14 MR. FARIES: Objection to form. 15 THE WITNESS: Yes, some women may have 16 those mutations without a reported family 17 history. 18 BY MR. KLATT: 19 Q. And so that's why increasingly women with 20 ovarian cancer with or without a family history are 21 being encouraged to have these tests for inherited 22 genetic mutations, correct? 23 MR. FARIES: Objection to form. 24 THE WITNESS: That is my understanding. 25 Again, I am not a genetic counselor, a medical</p>	<p>1 to her, correct? 2 MR. FARIES: Objection to form. 3 THE WITNESS: I cannot say that because I 4 do not think that there is adequate data that's 5 reported. 6 BY MR. KLATT: 7 Q. If a woman has never had a baby, she's at 8 increased risk for ovarian cancer compared to women 9 who have had one or more children, correct? 10 A. We talk about it on a population level. 11 We do not -- would not refer to it on an individual 12 woman, an individual level, but on a population level, 13 women who have not had children are at higher risk for 14 ovarian cancer than women who have not. 15 Q. Does -- 16 A. I think I misspoke that at the end. Women 17 who have not had children or had a baby are at higher 18 risk than women who have had children. 19 Q. What's the magnitude of that increased 20 risk? 21 A. It is reported in many different studies 22 and it somewhat depends on the study population. I 23 cannot pull a relative risk specifically out of my 24 head, but in a general sense, typically a nulliparous 25 woman might -- I'm sorry, we typically talk about</p>

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<p>1 women who have had a baby, so parous women as compared</p> <p>2 to nulliparous women, relative risk in the range of .5</p> <p>3 to .7 are pretty commonly reported.</p> <p>4 Q. So that would mean that a woman who -- or</p> <p>5 women that have not had children would be at a 1.5 to</p> <p>6 1.7 increased risk of ovarian cancer compared to women</p> <p>7 who have had children?</p> <p>8 A. That -- that's in the range of what I</p> <p>9 think most studies have reported.</p> <p>10 Q. Does not having children cause ovarian</p> <p>11 cancer?</p> <p>12 MR. FARIES: Objection to form.</p> <p>13 THE WITNESS: Not having children is a</p> <p>14 risk factor for ovarian cancer and then there</p> <p>15 may be biologically plausible reasons why that</p> <p>16 would be the case.</p> <p>17 BY MR. KLATT:</p> <p>18 Q. Well, not having children is a consistent</p> <p>19 risk factor for ovarian cancer in the population of</p> <p>20 women, correct?</p> <p>21 A. That has been a consistently reported risk</p> <p>22 factor, yes.</p> <p>23 Q. And a risk factor in the range of 1.5 to</p> <p>24 1.7 is higher than what you think the overall risk</p> <p>25 factor for talc use in ovarian cancer is, correct?</p>	<p>1 as a reasonable biological mechanism, and I</p> <p>2 think that it is -- it is a hypothesis supported</p> <p>3 with a great deal of data.</p> <p>4 BY MR. KLATT:</p> <p>5 Q. And you said earlier in response to</p> <p>6 Mr. Hegarty's questions that the reason monthly</p> <p>7 ovulation can increase the risk of ovarian cancer is</p> <p>8 because monthly ovulation results in a consistent</p> <p>9 inflammatory process in which these reactive oxygen</p> <p>10 species are released which can damage the DNA which</p> <p>11 then, in turn, results in ovarian cancer, correct?</p> <p>12 MR. FARIES: Objection to form.</p> <p>13 THE WITNESS: That is a mechanism that has</p> <p>14 been described, yes.</p> <p>15 BY MR. KLATT:</p> <p>16 Q. But you -- just a minute ago you did call</p> <p>17 it the "inflammation hypothesis" of ovarian cancer,</p> <p>18 correct?</p> <p>19 A. I -- don't recall. I think I might have.</p> <p>20 Q. Is --</p> <p>21 MR. FARIES: Before we keep going to</p> <p>22 something new, we've been going over an hour.</p> <p>23 MR. KLATT: Sure.</p> <p>24 MR. FARIES: I know you haven't, but let's</p> <p>25 take a short break.</p>
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<p>1 MR. FARIES: Objection to form.</p> <p>2 THE WITNESS: Yes.</p> <p>3 BY MR. KLATT:</p> <p>4 Q. And so you'd consider not having a</p> <p>5 child -- or women not having children a cause of</p> <p>6 ovarian cancer, correct?</p> <p>7 MR. FARIES: Objection to form.</p> <p>8 THE WITNESS: I think that not having</p> <p>9 children, it can -- because of various reasons,</p> <p>10 for example, we have talked about ovulation</p> <p>11 women -- that is one possible mechanism, so</p> <p>12 women who have not had children on average would</p> <p>13 have had more ovulations than women who have had</p> <p>14 multiple pregnancies. And so through this</p> <p>15 mechanism of the, you know -- again, ovulation</p> <p>16 is one of the risk factors that plays into the</p> <p>17 inflammation hypothesis. So through that</p> <p>18 pathway, one possible pathway, we could say not</p> <p>19 having children would -- could cause ovarian</p> <p>20 cancer.</p> <p>21 BY MR. KLATT:</p> <p>22 Q. So at this point, inflammation being a</p> <p>23 cause of ovarian cancer is just a hypothesis, correct?</p> <p>24 MR. FARIES: Objection to form.</p> <p>25 THE WITNESS: I -- it has been described</p>	<p>1 MR. KLATT: Absolutely. And I'm going</p> <p>2 to -- that will give me some time to --</p> <p>3 MR. FARIES: Okay, good.</p> <p>4 MR. KLATT: -- go through.</p> <p>5 (RECESS TAKEN FROM 6:09 P.M. TO 6:20 P.M.)</p> <p>6 BY MR. KLATT:</p> <p>7 Q. Would you agree, Dr. Moorman, that women</p> <p>8 who have had more lifetime ovulatory cycles may have</p> <p>9 used more talc-based body powder in conjunction with</p> <p>10 those ovulatory cycles over their lifetime?</p> <p>11 MR. FARIES: Objection to form.</p> <p>12 THE WITNESS: I have not looked at that</p> <p>13 particular question.</p> <p>14 BY MR. KLATT:</p> <p>15 Q. And you're aware that several factors can</p> <p>16 cluster together sometimes like that, correct, where</p> <p>17 you have kind of similar factors clustering together</p> <p>18 that are hard to parse out?</p> <p>19 MR. FARIES: Objection to form.</p> <p>20 THE WITNESS: Sometimes there are risk</p> <p>21 factors that are more common together.</p> <p>22 BY MR. KLATT:</p> <p>23 Q. So you never looked to see whether women</p> <p>24 who have more lifetime ovulatory cycles also have used</p> <p>25 more lifetime talcum powder in the genital area than</p>

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<p style="text-align: right;">Page 314</p> <p>1 women who have had fewer lifetime ovulatory cycles?</p> <p>2 A. I don't recall looking at that specific</p> <p>3 piece of data.</p> <p>4 Q. And that could be a confounding factor,</p> <p>5 correct?</p> <p>6 MR. FARIES: Objection to form.</p> <p>7 THE WITNESS: Yes. If they are related</p> <p>8 and they are both risk factors with a condition,</p> <p>9 that could be a potential confounder.</p> <p>10 BY MR. KLATT:</p> <p>11 Q. You know -- you talked earlier about the</p> <p>12 Gonzalez Sister Study, correct?</p> <p>13 A. Yes, I did mention that study.</p> <p>14 Q. And that was a big prospective study,</p> <p>15 correct?</p> <p>16 MR. FARIES: Objection to form.</p> <p>17 THE WITNESS: It was a prospective study</p> <p>18 with about 40,000 women and about 150 ovarian</p> <p>19 cancer cases.</p> <p>20 BY MR. KLATT:</p> <p>21 Q. And those women were at higher risk than</p> <p>22 average for ovarian cancer because the condition of</p> <p>23 participating in the study was that you had a sister</p> <p>24 who had had breast cancer, correct?</p> <p>25 A. That is correct.</p>	<p style="text-align: right;">Page 316</p> <p>1 talc in the genital area, correct?</p> <p>2 MR. FARIES: Objection to form.</p> <p>3 THE WITNESS: They reported a relative</p> <p>4 risk, I believe, of about .76 for talc use based</p> <p>5 on a fairly small number of exposed cases for</p> <p>6 both of those exposures.</p> <p>7 BY MR. KLATT:</p> <p>8 Q. But they did detect a fairly large</p> <p>9 increased risk of ovarian cancer in women who've used</p> <p>10 the vaginal douching products, correct?</p> <p>11 A. They did. As I answered, it was a</p> <p>12 significantly increased risk.</p> <p>13 Q. Doesn't that suggest on a population level</p> <p>14 that women who engage in various feminine hygiene</p> <p>15 practices in the genital area, whether it's use of</p> <p>16 talc or whether it's use of vaginal douching products</p> <p>17 or whatever, there's something about that population</p> <p>18 that puts them at higher risk for ovarian cancer than</p> <p>19 women who don't engage in those practices?</p> <p>20 MR. FARIES: Objection to form.</p> <p>21 THE WITNESS: This was a single study that</p> <p>22 reported on this. I would not make a conclusion</p> <p>23 on a single study like that. And as I</p> <p>24 indicated, they had a very -- a month --</p> <p>25 particularly among the ovarian cancer cases,</p>
<p style="text-align: right;">Page 315</p> <p>1 Q. And if you're a woman who's had a sister</p> <p>2 who's had breast cancer, you're at above average risk</p> <p>3 for ovarian cancer compared to women who haven't had a</p> <p>4 sister with breast cancer, right?</p> <p>5 A. Once again, on a population level, women</p> <p>6 with a family history of breast cancer are at higher</p> <p>7 risk for ovarian cancer as well.</p> <p>8 Q. And that would include women who've had a</p> <p>9 sister with breast cancer, correct?</p> <p>10 A. A sister with breast cancer is part of the</p> <p>11 family history, yes.</p> <p>12 Q. And so in the Gonzalez Sister Study, those</p> <p>13 women were at -- the whole population of study were at</p> <p>14 higher-than-average risk for ovarian cancer, correct?</p> <p>15 A. One would make that assumption based on</p> <p>16 their family history, yes.</p> <p>17 Q. And the Gonzalez Sister Study found a</p> <p>18 strong association between vaginal douching practices</p> <p>19 and ovarian cancer, correct?</p> <p>20 MR. FARIES: Objection to form.</p> <p>21 THE WITNESS: They did report a</p> <p>22 significantly increased risk as I recall.</p> <p>23 BY MR. KLATT:</p> <p>24 Q. Even though they didn't report any</p> <p>25 increased risk of ovarian cancer in women who used</p>	<p style="text-align: right;">Page 317</p> <p>1 they had a quite small number of women who</p> <p>2 reported use of either talc or reported</p> <p>3 douching.</p> <p>4 BY MR. KLATT:</p> <p>5 Q. You'd agree -- would you agree with me</p> <p>6 that if a woman has a tendency to perspire, she may be</p> <p>7 more likely to use talc-based body powders</p> <p>8 particularly in the genital area?</p> <p>9 MR. FARIES: Objection to form.</p> <p>10 THE WITNESS: I have not seen any data to</p> <p>11 support that one way or the other.</p> <p>12 BY MR. KLATT:</p> <p>13 Q. Well, let me ask you a hypothetical. If</p> <p>14 there's some genetic or hormonal factor that makes</p> <p>15 women more likely to perspire and that hormonal or</p> <p>16 genetic factor is associated with an increased risk of</p> <p>17 ovarian cancer, then you could confound the</p> <p>18 relationship with talc use, correct?</p> <p>19 MR. FARIES: Objection to form.</p> <p>20 BY MR. KLATT:</p> <p>21 Q. Do you understand what I'm saying?</p> <p>22 MR. FARIES: Same objection.</p> <p>23 THE WITNESS: You are describing a very</p> <p>24 hypothetical situation, and hypothetically it is</p> <p>25 possible, but, again, I don't think there is any</p>

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<p style="text-align: right;">Page 318</p> <p>1 data -- there's no data that I'm aware of that 2 would suggest what you hypothesized is the case. 3 BY MR. KLATT: 4 Q. Do you have any information on how the 5 population of women who use talc-based body powders in 6 the genital area differ as a population from women who 7 choose not to do that? 8 MR. FARIES: Objection to form. 9 THE WITNESS: Some -- I believe that some 10 papers have reported on characteristics of the 11 women who reported talc use and those that did 12 not. 13 BY MR. KLATT: 14 Q. And can you tell us any differences 15 between those two populations, the women who as a 16 population choose to use talc in the genital area and 17 the women who as a population choose not to use talc? 18 A. I have seen, I believe, in some papers 19 that women with higher BMIs might be more likely to 20 report talc. 21 Q. And you think high BMI is a cause of 22 ovarian cancer, don't you? 23 MR. FARIES: Objection to form. 24 THE WITNESS: It has certainly been 25 associated with ovarian cancer in multiple</p>	<p style="text-align: right;">Page 320</p> <p>1 mechanism, so it is -- I think my opinion is that it 2 could be a cause of ovarian cancer. 3 Q. You've published that there's a strong 4 association between weight gain past age 18 and 5 ovarian cancer, right? 6 A. Yes, we have published on that. 7 Q. And you've talked about something called 8 adipokines that are substances that fat in the body 9 produces that can increase inflammation and cause 10 ovarian cancer, right? 11 A. I think that you are referring to a paper 12 done by the's AACES -- based on the AACES study that 13 was either by Elisa Bandera or Bo Qin. 14 Q. Sounds familiar, yes. 15 A. Okay. And -- 16 Q. That you were a coauthor on? 17 A. Yes, I was a coauthor. And, again, on 18 those papers, off the top of my head, I can't recall 19 every sentence that was -- were in those papers. 20 Q. Are you familiar with the concept that 21 these adipokines are produced by fat tissue and can 22 cause chronic inflammation that may result in ovarian 23 cancer? 24 A. I am familiar with that concept in whole. 25 Q. And obesity leads to a state of chronic</p>
<p style="text-align: right;">Page 319</p> <p>1 studies, yes. 2 BY MR. KLATT: 3 Q. But you believe more than that, you 4 believe obesity, high BMI is a cause of ovarian 5 cancer, correct? 6 MR. FARIES: Objection. Slow down. 7 Objection to form. 8 THE WITNESS: Okay. I want to maybe 9 clarify my responses in this regard. None of 10 the risk factors that we have discussed, I have 11 not reviewed the literature in the same detail 12 as I have the talc powder and gone through the 13 same process of considering all the Bradford 14 Hill criteria, and so I -- my opinion is 15 strongest about talc. The other factors that I 16 considered, I do want to make the notation that 17 I have not done the review of all of those risk 18 factors in the detail that I have with the talc. 19 BY MR. KLATT: 20 Q. Do you believe obesity is or is not a 21 cause of ovarian cancer as you -- based on the 22 information you have as we sit here today? 23 A. Again, I have not done the review in the 24 same level of detail, but it is a consistently 25 reported risk factor with a biologically plausible</p>	<p style="text-align: right;">Page 321</p> <p>1 inflammation, correct? 2 MR. FARIES: Objection to form. 3 THE WITNESS: Yes. 4 BY MR. KLATT: 5 Q. And it -- I'm sorry, go ahead. 6 A. Yes, that has been reported. 7 Q. And it -- and obesity also leads to immune 8 suppression, correct? 9 MR. FARIES: Objection to form. 10 THE WITNESS: I am less familiar. I just 11 can't recall. 12 BY MR. KLATT: 13 Q. Haven't you said that in an article 14 before? 15 A. As I have indicated, this was a paper 16 written by a group of investigate -- a large group of 17 investigators on the study, and I cannot recall every 18 sentence that was written in it, you know, in that 19 paper. 20 Q. Right. But you were one of these authors, 21 correct? 22 A. We are -- again, the paper that we are 23 talking about is which paper? 24 Q. Let me see. I think you said the name of 25 the person correctly. Did you say Bandera? Is that</p>

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<p>1 the name that you threw out?</p> <p>2 A. That is our coauthor or our</p> <p>3 coinvestigator, I believe, wrote the paper on obesity.</p> <p>4 Q. And, again, this is something you were a</p> <p>5 coauthor on and had a chance to review before it went</p> <p>6 to publication, correct?</p> <p>7 A. Yes.</p> <p>8 Q. You're aware of something called</p> <p>9 interview -- interviewer bias, correct?</p> <p>10 A. Yes, I am.</p> <p>11 Q. And that's when someone interviewing the</p> <p>12 women who have ovarian cancer or interviewing the</p> <p>13 healthy women who are the controls somehow tips off</p> <p>14 the -- what they're interested in and encourages a</p> <p>15 response from one or the other, correct?</p> <p>16 A. That is how interviewer bias is typically</p> <p>17 described in textbooks, yes.</p> <p>18 Q. And you talked earlier about something</p> <p>19 called recall bias where women with a disease like</p> <p>20 ovarian cancer may rack their brains to remember an</p> <p>21 exposure that healthy women may not recall; is that</p> <p>22 correct?</p> <p>23 MR. FARIES: Objection to form.</p> <p>24 THE WITNESS: Recall bias, yes, is the</p> <p>25 potential bias that can result if women with the</p>	<p>1 more forthcoming about that than the healthy people</p> <p>2 who don't want to confess up to the use of alcohol?</p> <p>3 A. You are talking about recall bias and</p> <p>4 acknowledge that it is a possibility, and I think that</p> <p>5 it is very useful to consider empirical data that</p> <p>6 compared findings from case control studies versus</p> <p>7 cohort studies. Okay. And there was such a paper</p> <p>8 that was published within the last couple of years,</p> <p>9 and they compared what were the -- they took a random</p> <p>10 sample of meta-analyses that had been performed and</p> <p>11 compared the results from the case control studies</p> <p>12 where potential for recall bias versus the prospective</p> <p>13 cohorts where you would not expect recall bias. And</p> <p>14 their overall conclusion based on all of these studies</p> <p>15 was that there was not consistently higher odds ratios</p> <p>16 reported from the case control studies than the cohort</p> <p>17 studies, so there is, yes, the theoretical</p> <p>18 possibility. There is also a lot of empirical data</p> <p>19 suggesting that it is not always a problem and . . .</p> <p>20 Q. But we haven't -- you're not talking</p> <p>21 specifically about the studies that have looked at</p> <p>22 talc body powder use in ovarian cancer, correct?</p> <p>23 A. No. This is a variety of exposures and</p> <p>24 outcomes that these authors examined.</p> <p>25 Q. And, in fact, as you said earlier today,</p>
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<p>1 condition of interest recall things differently</p> <p>2 from the women who do not have that condition.</p> <p>3 BY MR. KLATT:</p> <p>4 Q. And it can also exist when -- and maybe</p> <p>5 it's called something else, but recall bias may also</p> <p>6 exist when healthy controls are hesitant to admit to</p> <p>7 something in their past, like something they perceive</p> <p>8 as embarrassing, like, perhaps, genital talc use,</p> <p>9 correct?</p> <p>10 A. Yes, we would -- when there is</p> <p>11 differential reporting between cases and controls,</p> <p>12 yes.</p> <p>13 Q. There was a spurious relation between</p> <p>14 women having abortions and breast cancer because women</p> <p>15 who had breast cancer gave accurate histories about</p> <p>16 abortion, but healthy women were hesitant to volunteer</p> <p>17 that information, correct?</p> <p>18 A. I have seen that study, yes.</p> <p>19 Q. And also, similarly, in studies -- you've</p> <p>20 done studies of alcohol intake, correct?</p> <p>21 A. That has been a factor that we have looked</p> <p>22 at in our studies, yes.</p> <p>23 Q. And sometimes in epidemiology studies</p> <p>24 people -- when they're talking about alcohol</p> <p>25 consumption, people with an illness or disease may be</p>	<p>1 in the talc-based body powder in ovarian cancer</p> <p>2 studies, we saw different outcomes from the</p> <p>3 prospective studies, prospective cohort studies</p> <p>4 compared to the population-based case control studies,</p> <p>5 correct?</p> <p>6 MR. FARIES: Objection to form.</p> <p>7 THE WITNESS: Yes, I did say that those --</p> <p>8 the results were . . .</p> <p>9 BY MR. KLATT:</p> <p>10 Q. But my earlier point just that I was</p> <p>11 trying to make a few minutes ago and I just want to</p> <p>12 make sure you agree with it, is that this phenomenon</p> <p>13 of recall bias can affect both women who had the</p> <p>14 disease and may be more motivated to recall past</p> <p>15 exposures, but it can also operate in the healthy</p> <p>16 people who may be more reluctant to admit to certain</p> <p>17 past behaviors or uses?</p> <p>18 A. Yes, it is possible that there is</p> <p>19 differential reporting in both directions.</p> <p>20 Q. Are you aware that there can be false</p> <p>21 negative results in women who are tested for BRCA1 and</p> <p>22 2 mutations? In other words, women are test -- who</p> <p>23 have ovarian cancer are tested to see if they have the</p> <p>24 BRCA1 or BRCA2 mutations, the test says they don't,</p> <p>25 but, in fact, they do have those. Are you aware of</p>

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<p>1 that?</p> <p>2 MR. FARIES: Objection to form.</p> <p>3 THE WITNESS: Once again, I am not a</p> <p>4 genetic -- genetic counselor or a geneticist,</p> <p>5 but . . .</p> <p>6 BY MR. KLATT:</p> <p>7 Q. Well, I had read an article of yours that</p> <p>8 you were the first author of called Evaluation of</p> <p>9 Established Breast Cancer Risk Factors as Modifiers of</p> <p>10 BRCA1 or BRCA2: A Multi-Center Case-Only Analysis.</p> <p>11 Do you recall that paper?</p> <p>12 A. I do recall that paper.</p> <p>13 Q. And one of the things that that paper</p> <p>14 stated is that there may be false negative results</p> <p>15 where women who actually do have BRCA1 or BRCA</p> <p>16 mutations test negative that they don't have them.</p> <p>17 A. Yes, I have heard that, but, again, I'm</p> <p>18 not a geneticist.</p> <p>19 Q. You've done studies that show that women</p> <p>20 who eat a lot of red meat and carbohydrates, that's</p> <p>21 called a pro-inflammatory diet, correct?</p> <p>22 A. There were investigators on the AACES</p> <p>23 study that did, in fact, examine that.</p> <p>24 Q. And were you a coauthor on any paper that</p> <p>25 looked at that?</p>	<p>1 A. Yes.</p> <p>2 Q. And you talked with Mr. Hegarty about that</p> <p>3 study showing that higher consumption of whole milk</p> <p>4 and lactose increased ovarian cancer risk, correct?</p> <p>5 A. Correct.</p> <p>6 Q. And that isn't the first time that's been</p> <p>7 shown in a study, correct?</p> <p>8 A. I'm sorry?</p> <p>9 Q. That wasn't -- your study that showed that</p> <p>10 whole milk consumption and higher lactose consumption</p> <p>11 increases the risk of ovarian cancer, that wasn't the</p> <p>12 first time a study had shown that, correct?</p> <p>13 A. I believe that that has been reported</p> <p>14 previously.</p> <p>15 Q. In fact, you all found that high lactose</p> <p>16 intake and high whole milk intake almost doubled the</p> <p>17 women's risk of ovarian cancer, right?</p> <p>18 A. Once again, I do not recall the specific</p> <p>19 odds ratios for those exposures, but I do recall some</p> <p>20 increased.</p> <p>21 Q. I'll represent to you the odds ratio was</p> <p>22 1.97 statistically significant. That -- if that's</p> <p>23 accurate, that would be almost a doubling of the risk,</p> <p>24 correct?</p> <p>25 A. That is correct.</p>
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<p>1 A. I believe that we did publish on that.</p> <p>2 Q. And did you find in your study that</p> <p>3 African-American women who had the highest</p> <p>4 pro-inflammatory diet consisting of red meat and</p> <p>5 carbohydrate consumption were at markedly increased</p> <p>6 risk of ovarian cancer compared to those women who had</p> <p>7 a low inflammatory diet?</p> <p>8 MR. FARIES: Objection to form.</p> <p>9 THE WITNESS: Again, recalling the exact</p> <p>10 odds ratios, that is my general sense of the</p> <p>11 paper as I recall it. I have not looked at that</p> <p>12 paper in detail in a while.</p> <p>13 BY MR. KLATT:</p> <p>14 Q. In another study you were involved in,</p> <p>15 showed that women who had more sun exposure had a</p> <p>16 reduced risk of ovarian cancer, right?</p> <p>17 A. Once again, I'm trying to recall. As you</p> <p>18 know, many papers came out of this study, many</p> <p>19 exposures considered, and many odds ratios reported.</p> <p>20 Can you -- I think you have a specific paper in mind?</p> <p>21 Q. Yes, it's one you talked about earlier</p> <p>22 with Mr. Hegarty. It was, I think, the Quin -- is</p> <p>23 that the correct pronunciation -- Q-U-I-N, study of</p> <p>24 dairy, calcium, vitamin D, and ovarian cancer risk in</p> <p>25 African-American women?</p>	<p>1 Q. And I believe in that same study you found</p> <p>2 that calcium intake -- increased calcium intake</p> <p>3 reduced the risk of ovarian cancer. Do you recall</p> <p>4 that?</p> <p>5 A. Once again, I'm having a little bit of</p> <p>6 trouble recalling all the specific odds ratios</p> <p>7 particularly for some of the papers where the -- I was</p> <p>8 not the lead author on.</p> <p>9 Q. Do you recall that same Quin paper showing</p> <p>10 that women who had more sunlight exposure had reduced</p> <p>11 risk of ovarian cancer?</p> <p>12 A. That is my general sense of it, but, once</p> <p>13 again, recalling the exact odds ratios is -- I don't</p> <p>14 recall the exact odds ratio.</p> <p>15 Q. Do you agree that recall bias and</p> <p>16 unidentified confounding factors could readily give</p> <p>17 rise to an odds ratio in the 1.2 to 1.3 range?</p> <p>18 MR. FARIES: Objection to form.</p> <p>19 THE WITNESS: I think that it depends.</p> <p>20 BY MR. KLATT:</p> <p>21 Q. But would you agree that when you have</p> <p>22 relative risk or odds ratios as low as 1.2 or 1.3,</p> <p>23 that is certainly within the range that could be</p> <p>24 affected by recall bias or unidentified confounding</p> <p>25 factors, correct?</p>

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<p style="text-align: right;">Page 330</p> <p>1 MR. FARIES: Objection to form.</p> <p>2 THE WITNESS: Again, I think that it</p> <p>3 depends on the factor that you're considering.</p> <p>4 BY MR. KLATT:</p> <p>5 Q. Well, let's be specific. That -- in the</p> <p>6 case of talc use in ovarian cancer, a relative risk</p> <p>7 that you said earlier is in the range of 1.2 or 1.3</p> <p>8 could be explained by recall bias and unidentified</p> <p>9 confounding factors, correct?</p> <p>10 MR. FARIES: Objection to form.</p> <p>11 THE WITNESS: I think that it is important</p> <p>12 to consider how they would come into play. We</p> <p>13 asked about talc in our questionnaire. That is</p> <p>14 a very extensive questionnaire. And some of the</p> <p>15 factors we asked about were hypothesized to</p> <p>16 increased risk, some decreased risk. And so</p> <p>17 when a woman is going through a questionnaire</p> <p>18 like this, it is hard to think that she has</p> <p>19 recalled, that she has given a great deal of</p> <p>20 thought to talc use, and so she recalls it</p> <p>21 differently than a women who does not have</p> <p>22 ovarian cancer.</p> <p>23 BY MR. KLATT:</p> <p>24 Q. Well, you've already said that recall</p> <p>25 could be affected by things like media attention to</p>	<p style="text-align: right;">Page 332</p> <p>1 was consistent with there being either no risk at all</p> <p>2 or even a decreased risk, correct?</p> <p>3 A. The range of the confidence interval, yes,</p> <p>4 was from .87 to 1.63.</p> <p>5 Q. But then if the women with ovarian cancer</p> <p>6 just happened to be interviewed after 2014, their</p> <p>7 reported talc use jumped from around 34, 35 percent</p> <p>8 suddenly up to 51 percent, correct?</p> <p>9 MR. FARIES: Objection to form.</p> <p>10 THE WITNESS: That is what our data show.</p> <p>11 BY MR. KLATT:</p> <p>12 Q. And you'd agree with me that when you're</p> <p>13 interviewing a woman about ovarian cancer and you're</p> <p>14 asking specifically about genital talc use, that may</p> <p>15 plant an idea in her head that there's something about</p> <p>16 that practice related to ovarian cancer, correct?</p> <p>17 MR. FARIES: Objection to form.</p> <p>18 THE WITNESS: I -- could it plant that</p> <p>19 idea? Once again, this -- these are a few</p> <p>20 questions in a very extensive questionnaire, and</p> <p>21 I don't think that -- very honestly, I don't</p> <p>22 think that women were giving a whole lot of</p> <p>23 thought to it.</p> <p>24 BY MR. KLATT:</p> <p>25 Q. Well, it's the only thing in the</p>
<p style="text-align: right;">Page 331</p> <p>1 the issue, correct?</p> <p>2 MR. FARIES: Objection to form.</p> <p>3 THE WITNESS: We did consider that in our</p> <p>4 study. And it's important to bear in mind, in</p> <p>5 the entire body of literature, the AACES study,</p> <p>6 to my knowledge, is the only one that continued</p> <p>7 to collect data in the time frame when there may</p> <p>8 have been media attention about talc in relation</p> <p>9 to ovarian cancer. So it is hard to say that --</p> <p>10 I mean, it would not be reasonable to say that</p> <p>11 media attention could have led to recall bias in</p> <p>12 the multiple other studies that have looked at</p> <p>13 talc and ovarian cancer.</p> <p>14 BY MR. KLATT:</p> <p>15 Q. But in that AACES study you're talking</p> <p>16 about before 2014, if the women were interviewed</p> <p>17 before 2014, there was no increased risk of ovarian</p> <p>18 cancer in talc users, correct?</p> <p>19 A. We reported -- once again, going back to</p> <p>20 it, the women who reported any genital use before</p> <p>21 2014, the odds ratio was 1.19, so pretty close to what</p> <p>22 many other studies have reported, and I do acknowledge</p> <p>23 that that was not a statistically significantly</p> <p>24 increased risk.</p> <p>25 Q. And, in fact, the confidence intervals, it</p>	<p style="text-align: right;">Page 333</p> <p>1 questionnaire that implies some sort of genital</p> <p>2 exposure, correct?</p> <p>3 A. We also ask about other genital</p> <p>4 conditions, so . . . Okay.</p> <p>5 Q. Well, that's a good point. The OCAC</p> <p>6 organization, are you a part of that?</p> <p>7 A. Not currently, no.</p> <p>8 Q. Okay. You're aware that they have found</p> <p>9 no relationship between pelvic inflammatory disease</p> <p>10 and serous ovarian cancer, right?</p> <p>11 MR. FARIES: Objection to form.</p> <p>12 THE WITNESS: I know that they have</p> <p>13 published on that, yes.</p> <p>14 BY MR. KLATT:</p> <p>15 Q. And that would be -- that finding is</p> <p>16 inconsistent with the notion that chronic inflammation</p> <p>17 can increase ovarian cancer, correct?</p> <p>18 MR. FARIES: Objection to form.</p> <p>19 THE WITNESS: Not necessarily.</p> <p>20 BY MR. KLATT:</p> <p>21 Q. Doesn't pelvic inflammatory disease</p> <p>22 involve inflammation of the fallopian tubes and the</p> <p>23 ovaries?</p> <p>24 MR. FARIES: Objection to form.</p> <p>25 THE WITNESS: Pelvic inflammatory disease,</p>

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<p>1 yes, I acknowledge that it can cause -- you</p> <p>2 know, as the name implies, it does cause</p> <p>3 inflammation. And my understanding is that this</p> <p>4 is a condition that is not -- is sometimes not</p> <p>5 accurately reported. Women may confuse pelvic</p> <p>6 inflammatory disease with other genital</p> <p>7 conditions.</p> <p>8 BY MR. KLATT:</p> <p>9 Q. But pelvic inflammatory disease is -- can</p> <p>10 be a chronic inflammatory condition of the fallopian</p> <p>11 tubes and the ovaries, correct?</p> <p>12 A. Yes.</p> <p>13 Q. Are you familiar with an epidemiologist</p> <p>14 named Kenneth Rothman?</p> <p>15 A. Yes.</p> <p>16 Q. And how do you know him?</p> <p>17 A. I do not know him personally. He has</p> <p>18 written several textbooks.</p> <p>19 Q. Is he -- is he a well-recognized</p> <p>20 epidemiologist?</p> <p>21 A. Yes, he is.</p> <p>22 Q. Is he well regarded in the field?</p> <p>23 A. Yes.</p> <p>24 Q. And on your reliance materials on page 11,</p> <p>25 you cited his textbook Modern Epidemiology as one of</p>	<p>1 certainty about risk factors that ranged from</p> <p>2 hypothetical risk factors to -- all the way to</p> <p>3 established risk factors?</p> <p>4 A. I believe that I did say something in that</p> <p>5 regard and, again, based on the level of knowledge</p> <p>6 that we have at a given point in time.</p> <p>7 Q. So somebody can talk about a risk factor,</p> <p>8 but it may just be hypothetical or uncertain, and at</p> <p>9 another time somebody may talk about a risk factor and</p> <p>10 it be an established risk factor, correct?</p> <p>11 MR. FARIES: Objection to form.</p> <p>12 THE WITNESS: I think that the modifier</p> <p>13 that you use is very important, so early in the</p> <p>14 evaluation of a factor, someone may think --</p> <p>15 there may be reason to think that this factor is</p> <p>16 associated with an increased risk of disease,</p> <p>17 but if you do not have a good body of evidence,</p> <p>18 it would be appropriate to describe that as a</p> <p>19 hypothesized risk factor.</p> <p>20 BY MR. KLATT:</p> <p>21 Q. You said in response to Mr. Hegarty's</p> <p>22 question earlier today that overall you would put the</p> <p>23 relative risk or odds ratio of talc-based body powder</p> <p>24 use in ovarian cancer in the 1.2 to 1.3 range,</p> <p>25 correct?</p>
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<p>1 your reliance materials, correct?</p> <p>2 A. You mean --</p> <p>3 Q. Down near the bottom of page 11.</p> <p>4 A. Yes.</p> <p>5 Q. What exhibit are you looking at right now?</p> <p>6 MR. FARIES: Three -- no, I'm sorry.</p> <p>7 THE WITNESS: Three.</p> <p>8 MR. FARIES: Three.</p> <p>9 BY MR. KLATT:</p> <p>10 Q. That's the reliance list, correct?</p> <p>11 A. Yes.</p> <p>12 Q. Have you ever communicated in writing or</p> <p>13 verbally about the subject of talc use, talc-based</p> <p>14 body powder use in ovarian cancer with Colditz,</p> <p>15 Cramer, or Siemiatycki, who you mentioned earlier?</p> <p>16 A. Verbally or in writing, no, I have not.</p> <p>17 Q. Did I understand you to say earlier this</p> <p>18 morning that when you're -- on the subject of risk</p> <p>19 factors, risk factors can run the gamut from</p> <p>20 hypothetical risk factors, uncertain risk factors,</p> <p>21 unproven risk factors, all the way to established risk</p> <p>22 factors?</p> <p>23 A. I -- no, I did not -- I don't think I said</p> <p>24 that this morning.</p> <p>25 Q. I thought you said there was a spectrum of</p>	<p>1 MR. FARIES: Objection to form.</p> <p>2 THE WITNESS: That is the conclusion of</p> <p>3 most meta-analyses, and I do agree with that.</p> <p>4 BY MR. KLATT:</p> <p>5 Q. On a numerical basis, when you're talking</p> <p>6 about a 1.2 or 1.3 relative risk or odds ratio, that</p> <p>7 means in a group of 12 or 13 women who use talc and</p> <p>8 have ovarian cancer, 10 of them would have gotten it</p> <p>9 anyway, and only 2 or 3 can be attributable to their</p> <p>10 talc use, correct?</p> <p>11 MR. FARIES: Objection to form.</p> <p>12 THE WITNESS: When you -- the way that you</p> <p>13 described it, I wouldn't not agree with that.</p> <p>14 When we talk about population attributable</p> <p>15 fraction, we consider both the odds ratio or</p> <p>16 relative risk as well as the prevalence of the</p> <p>17 risk factor in the population. So you have to</p> <p>18 consider both of them to get an estimate of how</p> <p>19 many women -- the way that we put it, what</p> <p>20 proportion of the population could be</p> <p>21 attributable to talc use.</p> <p>22 BY MR. KLATT:</p> <p>23 Q. Well, doesn't a 1.2 or 1.3 relative</p> <p>24 risk -- let's take a hypothetical population of 10,000</p> <p>25 women with ovarian cancer and 10,000 women without --</p>

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<p>1 it means that in one group you may have 100 cases of</p> <p>2 ovarian cancer, and the other you may have 120 or 130,</p> <p>3 correct?</p> <p>4 A. And, I'm sorry, it's late in the day to do</p> <p>5 any math.</p> <p>6 Q. Sure. I understand.</p> <p>7 A. But yeah.</p> <p>8 Q. I'm just trying to define numerically what</p> <p>9 you mean when you say an odds ratio or a relative risk</p> <p>10 of 1.2 or 1.3. That means there's going to be a</p> <p>11 baseline of people that would have had ovarian cancer</p> <p>12 regardless, correct, and then you add the increased</p> <p>13 risk on top of that, correct?</p> <p>14 A. That is correct.</p> <p>15 Q. So that would mean in a group of, say, 12</p> <p>16 or 13 women with ovarian cancer who had used talc that</p> <p>17 10 of them would have gotten it anyway as a background</p> <p>18 rate, correct?</p> <p>19 MR. FARIES: Objection to form.</p> <p>20 THE WITNESS: Once again, you're stating</p> <p>21 it in a way that I don't really think about it</p> <p>22 that way. I don't -- the way you're describing</p> <p>23 it, I don't think that is a way that</p> <p>24 epidemiologists would typically say out of a</p> <p>25 small group of women which would have gotten it</p>	<p>1 THE WITNESS: We don't know that.</p> <p>2 BY MR. KLATT:</p> <p>3 Q. Well, you'd have to have a doubling of the</p> <p>4 risk to have more women, correct?</p> <p>5 MR. FARIES: Objection to form.</p> <p>6 BY MR. KLATT:</p> <p>7 Q. If your risk is 1 point -- lifetime risk</p> <p>8 is 1.4 without talc and 1.7 with talc, the majority of</p> <p>9 women would have still gotten ovarian cancer whether</p> <p>10 they used talc or not, right?</p> <p>11 MR. FARIES: Objection to form.</p> <p>12 THE WITNESS: I think that is -- that --</p> <p>13 again, I think that is really hard to say who</p> <p>14 would have gotten it or not.</p> <p>15 BY MR. KLATT:</p> <p>16 Q. I'm not talking on an individual --</p> <p>17 A. Okay.</p> <p>18 Q. -- level, Dr. Moorman. I'm talking on a</p> <p>19 population level. If your risk, lifetime risk of</p> <p>20 ovarian cancer if you've never used talc is</p> <p>21 1.4 percent, and then according to what you've said,</p> <p>22 if you use talc, that 1.4 percent risk increases to a</p> <p>23 1.7 percent lifetime risk --</p> <p>24 A. Right.</p> <p>25 Q. -- the majority of ovarian cancers would</p>
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<p>1 regardless of whether or not they had used talc.</p> <p>2 BY MR. KLATT:</p> <p>3 Q. But the reason you compare a group of</p> <p>4 exposed women to a group of unexposed women is you</p> <p>5 want to know what that background rate is, correct,</p> <p>6 how many women would have had ovarian cancer whether</p> <p>7 or not they used talc, correct?</p> <p>8 A. Yes, when we calculate a relative risk,</p> <p>9 we're comparing what is the rate in the women who used</p> <p>10 talc compared to those who did not.</p> <p>11 Q. So in a group of 100 -- 100 women who</p> <p>12 didn't use talc but had ovarian cancer compared to a</p> <p>13 group of women who used talc, that 1.2, 1.3 would mean</p> <p>14 120 or 130 of women in the talc group developed</p> <p>15 ovarian cancer compared to the 100 women in the</p> <p>16 nontalc group, correct?</p> <p>17 A. So, again, if we're looking in the overall</p> <p>18 population, and we have talked about this, the</p> <p>19 estimated lifetime risk is about 1.3 to 1.4 percent,</p> <p>20 and then we would expect that to be about 25 percent</p> <p>21 higher among women who use talc.</p> <p>22 Q. But the majority of women who use talc</p> <p>23 would have gotten their ovarian cancer anyway,</p> <p>24 correct?</p> <p>25 MR. FARIES: Objection to form.</p>	<p>1 have occurred in women whether or not they used talc,</p> <p>2 correct?</p> <p>3 MR. FARIES: Objection to form.</p> <p>4 THE WITNESS: I'm --</p> <p>5 MR. FARIES: Just answer the best you can.</p> <p>6 If you can answer, you can. If you can't, just</p> <p>7 tell him you're unable to answer the question.</p> <p>8 THE WITNESS: Yeah, I -- you know, again,</p> <p>9 it's -- I think that, you know, where -- what</p> <p>10 would have happened in the absence of talc use,</p> <p>11 and, you know, there -- we're looking at the</p> <p>12 overall population.</p> <p>13 BY MR. KLATT:</p> <p>14 Q. And the majority of women if they hadn't</p> <p>15 used talc would have still developed ovarian cancer</p> <p>16 who eventually developed it, right?</p> <p>17 MR. FARIES: Objection to form.</p> <p>18 THE WITNESS: Yeah.</p> <p>19 BY MR. KLATT:</p> <p>20 Q. You're talking about --</p> <p>21 A. I --</p> <p>22 Q. You know what I'm talking about.</p> <p>23 A. Yeah.</p> <p>24 Q. Don't you? You're talking about a</p> <p>25 1.4 percent lifetime risk if you've never used talc,</p>

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<p>1 and then according to you, it increases three-tenths 2 of a percent to 1.7 if you have used talc, correct? 3 So the majority of women who develop ovarian cancer 4 would do it whether or not they used talc, correct? 5 MR. FARIES: Objection to form. 6 THE WITNESS: Can I just say I'm not 7 comfortable? 8 MR. FARIES: Yes. 9 MS. PARFITT: Yes, absolutely. 10 MR. FARIES: It's quite all right. 11 BY MR. KLATT: 12 Q. I just want to ask one or two things more. 13 Let me just -- I wasn't quite clear in your responses 14 to Mr. Hegarty's question. Do you believe that 15 postmenopausal hormone replacement therapy use causes 16 ovarian cancer or not? 17 A. Yeah, I think I'd like to clarify that. I 18 came to the conclusion about making the statement that 19 talc is a cause of ovarian cancer on the basis of a 20 very extensive review of the literature, and I did not 21 do that same process for all of the other risk factors 22 that were described there. And so I -- so I feel like 23 the evidence is -- does describe hormone -- menopausal 24 hormone therapy as a risk factor for breast cancer and 25 that I have not gone through the same process, and so</p>	<p>1 through the entire process of assessing the 2 causality in the same way that I applied the 3 criteria to talc, and so I am not -- I do very 4 definitely consider it a risk factor. I think 5 that it is a very -- that it's very probably a 6 cause for ovarian cancer. I just didn't go 7 through the same process. 8 BY MR. KLATT: 9 Q. I understand. 10 A. Okay. 11 Q. Okay. I think I'm done. 12 MR. FARIES: Mark, before you begin, how 13 many minutes do you need? 14 MR. HEGARTY: I probably need about 15 15 minutes. 16 MR. FARIES: Okay. Are you ready to 17 continue for 15 minutes? 18 THE WITNESS: Yes, let's just go ahead. 19 EXAMINATION 20 BY MR. HEGARTY: 21 Q. These are a few follow-up questions, so 22 I'm going to jump around a little bit. 23 A. Okay. 24 Q. Dr. Moorman, do you agree that you're not 25 an expert in interpreting internal company documents?</p>
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<p>1 I would maybe be a little bit more circumspect about 2 saying whether or not it is a cause because I haven't 3 gone through the same process. 4 Q. Well, you told us earlier today that 5 you're an expert on ovarian cancer epidemiology, 6 correct? 7 A. That is correct. 8 Q. There's been many, many studies of hormone 9 replacement therapy use in ovarian cancer, correct? 10 A. Yes. 11 Q. And those studies show a consistently 12 increased risk of ovarian cancer in women who use 13 hormone replacement therapy, correct? 14 MR. FARIES: Objection to form. 15 THE WITNESS: That is -- yes, I do. 16 BY MR. KLATT: 17 Q. And it's certainly at least within the 18 range of risk of 1.2, 1.3, or more, correct? 19 A. That is correct. 20 Q. Therefore, applying the same criteria 21 you've applied to talc, you would say that hormone 22 replacement therapy use is a cause of ovarian cancer, 23 correct? 24 MR. FARIES: Objection to form. 25 THE WITNESS: So, once again, I did not go</p>	<p>1 A. I do agree with that. 2 Q. It's not something you've ever been asked 3 to do before working on this case, correct? 4 A. That is correct. 5 Q. And it's fair to say you don't know any of 6 the individuals whose names are referenced in any 7 internal company documents that you looked at, 8 correct? 9 A. No, I do not know anybody. 10 Q. Is it also correct you don't have any 11 familiarity with J&J as a company and how it works 12 internally either currently or in years past? 13 A. No, I do not. 14 Q. For purposes of your opinions in this 15 case, did you factor into those opinions the Miners 16 and Millers studies of those who mined and milled talc 17 in looking at any increase in lung cancer in those 18 individuals? 19 MR. FARIES: Objection to form. 20 THE WITNESS: I considered all of the 21 literature, and I did read those papers, at 22 least some of them. 23 BY MR. HEGARTY: 24 Q. Is it your opinion that there is a 25 background level of talc in women's ovaries --</p>

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<p>1 MR. FARIES: Objection to -- 2 BY MR. HEGARTY: 3 Q. -- without regard to talcum powder use? 4 MR. FARIES: I'm sorry. Objection to 5 form. 6 BY MR. HEGARTY: 7 Q. Let me restate that. Is there a 8 background level of talc in women regardless of talcum 9 powder product use? 10 MR. FARIES: Objection to form. 11 THE WITNESS: I don't know. I don't know 12 the data to that. 13 BY MR. HEGARTY: 14 Q. Is there a background level of asbestos in 15 the ovaries of women regardless of exposure to 16 asbestos in the work -- in nonoccupational or 17 occupational situation? 18 MR. FARIES: Objection to form. 19 THE WITNESS: I don't know. 20 BY MR. HEGARTY: 21 Q. Do background -- does exposure to 22 background levels of asbestos cause ovarian cancer? 23 MR. FARIES: Objection to form. 24 THE WITNESS: I don't know that that's 25 ever been evaluated.</p>	<p>1 A. I cannot think of any. 2 Q. We also have covered a number of studies 3 over the course of today, correct? 4 A. That is correct. 5 Q. Are there any other studies that you 6 consider to be important enough to make sure that we 7 are aware of that we have not covered here today? 8 MR. FARIES: Objection to form. 9 THE WITNESS: I cannot think of any. 10 BY MR. HEGARTY: 11 Q. Are you currently involved or working on 12 any study looking at talcum powder exposure in ovarian 13 cancer? 14 A. I have already described to you the 15 studies that I am involved with, the AACES study as 16 well as the OCAC consortium, and those will be -- we 17 will continue to consider talc in the studies. 18 Q. Let me ask it a different way. Are you 19 currently working on any paper that's going to report 20 on an odds ratio or relative risk of talcum powder 21 exposure in ovarian cancer risk? 22 A. There is no such paper in process. 23 Q. I asked you about whether you looked at 24 the Miners and Millers studies for purposes of your 25 analysis in this case. Did you review the studies</p>
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<p>1 BY MR. HEGARTY: 2 Q. You were asked -- strike that. 3 You've reviewed with -- in advance of the 4 deposition the three Long or Longo studies at the end 5 of your disclosure statement. Do you remember that? 6 A. I did look at those. 7 Q. Do you have, in your opinion, sufficient 8 expertise to interpret those study results? 9 A. As we -- 10 MR. FARIES: Objection to form. 11 THE WITNESS: As we have established 12 before, I am not a mineral scientist. 13 BY MR. HEGARTY: 14 Q. Do you know the tests that are used to 15 look for asbestos in talc? 16 A. Once again, I am not -- that is not in my 17 area of expertise. 18 Q. Over the course of today, we've talked 19 about your opinions. Is that -- that's a fair 20 statement, correct? 21 A. Yes. 22 Q. Have there been any -- are there any other 23 opinions that you came in here thinking you -- or 24 knowing you want to make sure that you provided to us 25 that we have not covered here today?</p>	<p>1 looking at the use of talc as pleurodesis and whether 2 those studies reported an increase in the risk of 3 cancer? 4 A. I believe that I looked at one of those, 5 at least one of those studies at some point. 6 Q. Do you recall whether that study or those 7 studies showed an increase in the risk of any cancer 8 in the patients who have had talc use for pleurodesis? 9 A. My recollection is that based on overall 10 relatively small numbers, they did not report a 11 significantly increased risk of cancer. 12 Q. I should have asked this a moment ago: Do 13 you recall if the Miners and Millers studies reported 14 an increase in risk of any cancer in those workers? 15 MR. FARIES: Objection to form. 16 THE WITNESS: Right off the top of my 17 head, I do not recall exactly what they 18 reported. 19 BY MR. HEGARTY: 20 Q. I went past the Bradford Hill criteria of 21 coherence, analogy, and experiment. With regard to 22 those three, and we can break them out one at a -- are 23 there any particular studies or -- that went to your 24 analysis of those three? 25 MR. FARIES: Objection to form.</p>

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<p>1 THE WITNESS: I considered them -- the 2 experiment is the one that is easiest to deal 3 with when we are talking about an exposure like 4 talc that is thought to increase risk. There 5 would never be an experimental study, so like a 6 randomized control trial. So there is no 7 experimental evidence in humans to address this. 8 In terms of coherence, that is typically 9 described as, is there anything that seriously 10 contradicts what is generally -- our general 11 state of knowledge about this condition? And I 12 do not think that there is. 13 And analogy, even Bradford Hill describes 14 that as perhaps the weakest of the 15 considerations. So what are you going to make 16 an analogy to? You could say, for example, 17 there is an increased risk associated with 18 asbestos and ovarian cancer, so what would be 19 analogous to that? Could it be the potential 20 route of administration or route of exposure and 21 so on. But, again, that was not one of the 22 criteria that I would weight strongly because 23 Bradford Hill indicates it's perhaps the weakest 24 of the factors to consider. 25</p>	<p>1 as to talcum powder products causing ovarian cancer, 2 is there any way to determine a rate of error in that 3 opinion, that is, the rate by which you may be 4 incorrect? 5 MR. FARIES: Objection to form. 6 THE WITNESS: I don't know how one would 7 quantify that. 8 BY MR. HEGARTY: 9 Q. Mr. Klatt asked you whether you had any 10 communications with Drs. Colditz, Siemiatycki, and 11 Cramer. Have you had communications with any expert 12 who has testified in the talc litigation? 13 A. No, I have not. 14 Q. We asked about the potential for asbestos 15 to be involved in the -- your analysis. Do you intend 16 to offer any opinion that arsenic, heavy metals, or 17 anything else in talc causes ovarian cancer? 18 A. As I have stated before, my opinion is 19 about the talcum powder product as a whole and so 20 whatever its constituents may be. 21 Q. Have you done any separate analysis of 22 arsenic exposure in ovarian cancer? 23 A. No, I have not. 24 Q. Have you done any separate analysis of 25 heavy metal exposure in ovarian cancer?</p>
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<p>1 BY MR. HEGARTY: 2 Q. The last one that we didn't talk about and 3 you did mention is specificity. Did you -- what was 4 your analysis of specificity? 5 A. Again, that can be interpreted in 6 different ways. So one aspect of it would be is one 7 factor specifically related to -- is this a specific 8 cause? And when we consider that most cancers -- all 9 cancers probably have multiple causes, that the fact 10 that this ovarian cancer is not specifically and only 11 related to talc, that's -- again, it's a criteria, 12 but, again, not one of the strongest factors that I 13 considered. 14 Q. Is it your opinion that talc that is 15 ingested increases the risk of ovarian cancer? 16 MR. FARIES: Objection to form. 17 THE WITNESS: Can you define what you mean 18 by "ingested"? 19 BY MR. HEGARTY: 20 Q. Sure. If there is talc in food, does 21 ingesting that food increase the risk of ovarian 22 cancer, in your opinion? 23 A. In my opinion, that has not been studied, 24 and so I do not have an opinion on that specifically. 25 Q. With regard to the opinions that you have</p>	<p>1 A. No, I have not. 2 Q. I think that's all that I had. 3 MR. FARIES: Give us a short break, and 4 then we will wrap this up. 5 (RECESS TAKEN FROM 7:19 P.M. to 7:25 P.M.) 6 EXAMINATION 7 BY MR. FARIES: 8 Q. All right. Dr. Moorman, good evening. I 9 just want to clarify that the terms "talc" and "talcum 10 powder products" and "body powders" and variations 11 have been used off and on during your deposition 12 today. Do you recall that? 13 A. Yes, I do. 14 Q. And when you have used the word "talc" or 15 similarly, in fact, you're referring to talcum powder 16 products? 17 A. That is correct. 18 Q. Do you recall some extensive testimony 19 you've given tonight on Bradford Hill analysis or 20 similar? 21 A. Yes. 22 Q. Do you utilize Bradford Hill analysis or 23 similar methodologies in your practice as an 24 epidemiologist? 25 MR. HEGARTY: Objection, form.</p>

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<p>1 BY MR. FARIES: 2 Q. You can answer the question. 3 MR. KLATT: And, Steve, can one objection 4 be good for all? 5 MR. FARIES: Yes. 6 THE WITNESS: Yes. Bradford Hill criteria 7 or similar methodology are applied in my work, 8 yes. 9 BY MR. FARIES: 10 Q. And does that work include employing, 11 utilizing Bradford Hill criteria or analysis or 12 similar in your efforts ultimately resulting in 13 published scientific literature? 14 MR. HEGARTY: Objection, form. 15 THE WITNESS: Yes. 16 BY MR. FARIES: 17 Q. Okay. And do, in fact, published papers 18 including those of which you have as a coauthor or an 19 author discuss methods and analysis that were utilized 20 in order to reach discussion and results in a paper? 21 A. Yes. 22 Q. And are those methods and analysis akin to 23 a Bradford Hill criteria analysis? 24 MR. HEGARTY: Objection, form. 25 THE WITNESS: Yes.</p>	<p>1 A. Okay. 2 Q. I'm not asking about whether those are 3 established criteria. My question was and is: Have 4 you ever done the same analysis running through the 5 Bradford Hill criteria for any other exposure and any 6 other disease and came to an opinion as to causation 7 as you have done in this case? 8 A. Through -- I mean, throughout all of the 9 work that I've done, I've gone through this process 10 repeatedly, and whether I ever stated that it was a 11 cause, I more commonly would use "risk factor." 12 Q. So is it your testimony that where you 13 have stated in a publication that a particular factor 14 or particular exposure or event is a risk factor, that 15 in every instance you have gone through the Bradford 16 Hill criteria as you have done with regard to talcum 17 powder products and ovarian cancer? 18 MR. FARIES: Objection to form. 19 THE WITNESS: These are -- the Bradford 20 Hill considerations, they are just integrated 21 into my way of thinking about data and one would 22 consider a body of literature, so . . . 23 BY MR. HEGARTY: 24 Q. Let me give you an example, might make it 25 clearer. You have gone through the Bradford Hill</p>
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<p>1 BY MR. FARIES: 2 Q. Finally, in your role as an expert in this 3 case, have you utilized here the same Bradford Hill 4 analysis and other generally accepted epidemiologic 5 scientific methods as you use in your profession to 6 reach your opinions in this case? 7 MR. HEGARTY: Objection, form. 8 THE WITNESS: Yes. 9 MR. FARIES: Okay. No further questions. 10 MR. HEGARTY: Just a couple of follow-up 11 questions to those, just to those lines of 12 questions. 13 EXAMINATION 14 BY MR. HEGARTY: 15 Q. Dr. Moorman, can you identify in any other 16 context where you have done the same analysis and 17 reached a conclusion on causation as you have done in 18 this case? 19 A. I cannot think of -- I apply these -- you 20 know, as we described here, the considerations 21 described by Bradford Hill are used all the time in 22 my -- in my work. 23 Q. I understand -- 24 A. And -- 25 Q. I'm sorry, I didn't mean to interrupt.</p>	<p>1 criteria in this case and came to the conclusion that 2 talcum powder products caused ovarian cancer, correct? 3 A. Yes. 4 Q. What you've just told me is that you've 5 gone through that same criteria, for example, as to 6 obesity, correct? 7 MR. FARIES: Objection to form. 8 THE WITNESS: I have considered these 9 factors, and as I stated previously, I have not 10 reviewed that literature in the same detail that 11 I've reviewed the talc literature. 12 BY MR. HEGARTY: 13 Q. So you have done some analysis review 14 methodology here as to talcum powder products in 15 ovarian cancer that you have not done as to all the 16 other risk factors for ovarian cancer, correct? 17 MR. FARIES: Objection to form. 18 THE WITNESS: Once again, I have 19 considered all of these things in relation to 20 numerous risk factors and, again, stating I have 21 not done it to the same in-depth review of these 22 papers that I have done for talc. 23 BY MR. HEGARTY: 24 Q. And so you have not done the same in-depth 25 review for any other work you have published on risk</p>

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<p>1 factors that you have done in this case for talc, 2 correct? 3 MR. FARIES: No, objection to form. 4 BY MR. HEGARTY: 5 Q. You can answer. 6 A. Please repeat it. 7 Q. Would you read back my question? 8 (PREVIOUS QUESTION READ BACK BY THE REPORTER) 9 MR. FARIES: Objection to form. 10 THE WITNESS: I think that it is fair to 11 say that this is the most in-depth review that I 12 have done. I have done a similar consideration 13 of all of these factors in relation to other 14 risk factors. 15 BY MR. HEGARTY: 16 Q. Can you cite for me any paper in which you 17 have gone through the Bradford Hill criteria in your 18 evaluation of a risk factor? 19 A. We incorporate this methodology into 20 essentially every paper that we write. In our 21 discussion, we consider what other authors have 22 published on it. We -- so the consistency, the 23 strength. We consider the biological plausibility. 24 So I think that it is fair to say that this is 25 considered in virtually all of our publications.</p>	<p>1 BY MR. KLATT: 2 Q. So do you believe anything else other than 3 talc is a cause of ovarian cancer based on whatever 4 criteria you want to use? 5 MR. FARIES: Objection to form. It's been 6 asked and answered many times, and you can go 7 through the transcript and find all instances 8 where she's answered this question on a host of 9 risk factors. 10 MR. KLATT: Are you telling her not to 11 answer? 12 MR. FARIES: So what I instruct you to do 13 is tell him to -- I instruct you not to answer 14 the question. 15 Just go back and go over the transcript. 16 MR. KLATT: Well, all right. We may be 17 back, but . . . 18 MR. FARIES: Well, I think if you go 19 through the transcript, will be no need to be 20 back. 21 MR. KLATT: I'm not sure that's clear, but 22 if you're instructing her not to answer, that's 23 your risk. 24 MR. FARIES: Thank you. We're done. 25 7:35.</p>
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<p>1 Q. Mr. Faries asked you about Bradford Hill 2 and other epidemiological, I think he may have said, 3 criteria or concepts, and I'll let Mr. Faries jump in 4 if he can tell me which -- 5 MR. FARIES: Scientific epidemiology, 6 scientific methods. 7 BY MR. HEGARTY: 8 Q. What are -- are there any other, besides 9 Bradford Hill, epidemiologic and scientific methods 10 that you applied here? 11 A. The essence of the methodology is pretty 12 consistent. Some people may not refer to -- 13 specifically to Bradford Hill criteria, but they are 14 getting at the same concepts. 15 Q. Thank you. 16 MR. KLATT: Just one question. 17 EXAMINATION 18 BY MR. KLATT: 19 Q. Do you think any -- as an ovarian cancer 20 epidemiology expert, do you think there's anything 21 else other than talc that's a cause of ovarian cancer? 22 MR. FARIES: Objection, objection to form. 23 We have spent so much time on risk factors and 24 causes. 25 MR. KLATT: Yeah, and I'm not clear.</p>	<p>1 (SIGNATURE RESERVED) 2 (DEPOSITION CONCLUDED AT 7:35 P.M.) 3 - - - 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>

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Exhibit 24

Association between Body Powder Use and Ovarian Cancer: The African American Cancer Epidemiology Study (AACES)

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Abstract

Background: Epidemiologic studies indicate increased ovarian cancer risk among women who use genital powder, but this has not been thoroughly investigated in African American (AA) women, a group with a high prevalence of use. We evaluate the relationship between use of genital powder and nongenital powder in invasive epithelial ovarian cancer (EOC).

Methods: Subjects are 584 cases and 745 controls enrolled in the African American Cancer Epidemiology Study (AACES), an ongoing, population-based case-control study of EOC in AA women in 11 geographic locations in the United States. AA controls were frequency matched to cases on residence and age. Logistic regression was used to calculate ORs and 95% confidence intervals (CI) for associations between genital and nongenital powder exposure and EOC risk, controlling for potential confounders.

Results: Powder use was common (62.8% of cases and 52.9% of controls). Genital powder was associated with an increased risk of EOC (OR = 1.44; 95% CI, 1.11–1.86) and a dose-response relationship was found for duration of use and number of lifetime applications ($P < 0.05$). Nongenital use was also associated with EOC risk, particularly among non-serous EOC cases (OR = 2.28; 95% CI, 1.39–3.74). An association between powder use and upper respiratory conditions suggests an enhanced inflammatory response may explain the association between body powder and EOC.

Conclusions: In a study of AA women, body powder use was significantly associated with EOC risk.

Impact: The results support that body powder is a modifiable risk factor for EOC among AA women. *Cancer Epidemiol Biomarkers Prev*; 25(10); 1411–7. ©2016 AACR.

See related commentary by Trabert, p. 1369

Introduction

Genital powder use may be a modifiable risk factor for epithelial ovarian cancer (EOC), the most deadly of all gynecologic cancers (1). In 2010, the International Agency for

Research on Cancer (IARC) classified perineal (genital) use of nonasbestos-containing, talc-based body powder as "possibly" carcinogenic to humans (2). Although particles of asbestos have been found in older body powder formulations, particularly prior to 1976 (3), more recent body powder formulations no longer contain asbestos (4, 5). However, the relationship between genital powder use and ovarian cancer appears to persist (6). It has been proposed that talc-containing powders may promote cancer development through local inflammation, increased rates of cell division and DNA repair, increased oxidative stress, and increased cytokine levels (7).

A recent pooled analysis of eight population-based case-control studies demonstrated an elevated OR of 1.24 for the association between genital powder use and EOC (6). Some (7–15) but not all (6, 8, 16) previously published studies of talc and ovarian cancer reported a dose-response relationship with genital powder use for frequency, duration, or number of applications. In addition, some studies reported a stronger association among the most common serous histologic subtype (4, 10, 14, 16, 17) although the pooled analysis did not confirm this finding (6). Only one prospective study (17) found a significant association with ever genital talc use and invasive serous EOC (RR = 1.40; 95% CI, 1.02–1.91), although no overall association with EOC was found. The Women's Health Initiative (WHI; ref. 18) did not detect an association with

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genital talc use and EOC. Neither prospective study found evidence of a dose-response relationship.

Previous studies of genital powder use have included mostly white women. However, two studies reported analyses stratified by race and both found an increased EOC risk among African American (AA) women who used genital talc (14, 15). One study reported a nonsignificant association between one or more years of talc use and risk of ovarian cancer, OR = 1.56, [95% confidence interval (CI), 0.80–3.04] among a small sample of 128 AA EOC cases and 143 AA controls, who were shown to have higher prevalence of talc use compared with whites (14). A second study reported an imprecise but significant association with genital talc use with an OR of 5.08 (95% CI, 1.32–19.6) among a very small sample of 16 cases and 17 controls (15). In this article, we present analyses of the relationship between both genital powder and nongenital powder exposure from the African American Cancer Epidemiology Study (AACES), an ongoing, multicenter case-control study of invasive EOC in AA women.

Materials and Methods

Study population

AACES is an ongoing, population-based, case-control study of invasive EOC in AA women in 11 locations (Alabama, Georgia, Illinois, Louisiana, Michigan, New Jersey, North Carolina, Ohio, South Carolina, Tennessee, and Texas). Institutional review board approval was obtained from all participating institutions. Methods have been described in detail elsewhere (19). Briefly, cases include AA women 20 to 79 years of age with newly diagnosed EOC. With a goal of enrolling an equal number of cases and controls, controls were AA women identified through random digit dialing, with at least one intact ovary and no history of ovarian cancer, and frequency matched to cases on region of residence and 5-year age categories. Participants complete a baseline telephone interview, which includes detailed questions on demographic characteristics; reproductive, gynecologic, and medical history; hormone therapy (HT) and oral contraceptive (OC) use; cancer family history and lifestyle characteristics including smoking, alcohol consumption, and physical activity. In an effort to obtain information from as many women as possible, a short version of the questionnaire is offered to those who would otherwise refuse to participate in the study. Accrual began in December 2010 and as of August 31, 2015, 593 cases and 750 controls were enrolled. Eligibility for this analysis was restricted to participants for whom data on body powder use and all covariates were available, resulting in a final sample size of 584 cases and 745 controls; of these, 49 cases and 16 controls completed the short questionnaire.

Exposure to body powder and talc

In the baseline interview, participants were asked whether they had ever regularly used talc, cornstarch, baby, or deodorizing powders. Participants were considered "regular users" if they reported using any of these powders at least one time per month for at least 6 months, and "never users" if they did not. Regular users were asked about their frequency and duration of use, age at first use, and whether they applied powders to genital areas (including on underwear or sanitary napkins, or on birth control devices like diaphragms) and/or nongenital areas. Participants were categorized according to their type of

application as nongenital use only, genital use only, or genital and nongenital use. Lifetime number of applications was calculated by multiplying the number of body powder applications per month by the number of months used. Occupational exposure to talc (yes, no) was available only for subjects completing the long baseline survey.

Statistical analysis

The prevalence of demographic characteristics was calculated and *t* tests and χ^2 tests were performed to compare distributions between cases and controls. Because of the relatively small number of women who reported having only used genital powder (43 cases and 44 controls), we merged this exposure category with those who reported use of both nongenital and genital powder, creating an exposure category of "any" genital powder use. Unconditional multivariable logistic regression was performed to calculate ORs and 95% CIs for the associations between body powder exposure ("only" nongenital use, and "any" genital use) and risk of EOC. Body powder exposure was further examined by frequency of use (less than 30 times per month, daily), duration of use categorized as less than the median or the median and greater among the controls (<20 years, ≥ 20 years), and lifetime number of applications categorized as less than the median or the median and greater among controls (<3,600, $\geq 3,600$ lifetime applications). Trend tests for frequency, duration, and lifetime applications of powder use by route of exposure were conducted separately in two subsamples: only nongenital users plus never users and any genital users plus never users. For each subsample, each of the above variables was entered into a logistic regression as multiple indicator variables representing three levels and two degrees of freedom (i.e., for frequency of use: no exposure, less than daily, daily), adjusting for confounders. Trends were evaluated by statistical tests for the association between frequency/duration/lifetime applications with EOC risk, using Wald tests to simultaneously test the equality of parameter estimates with zero. Because experimental data suggest a relationship between inhaled inert particles and asthma (20), a logistic regression analysis was conducted to determine the association between body powder use and upper respiratory conditions (yes/no), controlling for EOC case/control status.

Covariates included reference age in years (age at diagnosis for cases and age at baseline interview for controls); study site [Alabama, Louisiana, New Jersey, North Carolina, Ohio, South Carolina, Texas, Michigan and Illinois (combined because of sample size and regional similarities), Georgia and Tennessee (combined because of sample size)]; education (\leq high school, some after high school training, college or graduate degree); parity (0, 1, 2, 3+); duration of oral contraceptives (never, <60 months, ≥ 60 months); history of tubal ligation (yes/no); family history of breast or ovarian cancer in a first-degree relative (yes/no); smoking (ever/never); and body mass index (BMI < 25, 25–29.9, ≥ 30 kg/m²). Two class action lawsuits were filed in 2014 (21) concerning possible carcinogenic effects of body powder, which may have influenced recall of use. Therefore, year of interview 2014 or later (yes/no) was included as a covariate in the logistic regression models. To assess potential reporting bias, we also examined whether there were differences in prevalence of reported powder use by interview year (before 2014, 2014 and later) for cases and controls as well as whether interview year was an effect modifier of the relationship between powder use and EOC risk.

Analyses by the histologic subtype versus all controls were also conducted and heterogeneity of risk estimates was tested by seemingly unrelated regression (22). Because of the missing data for histology, 48 cases were omitted from these analyses. Through stratified analyses, we also assessed possible effect modification of the association with powder use and ever use of HT among postmenopausal women using logistic regression. Experimental data show that the inflammatory response is enhanced in the presence of estrogen and progesterone and we therefore tested for interaction of the association with body powder use by menopausal status (20). Logistic regression and trend analyses were performed using SAS version 9.4 (SAS Institute).

Results

Descriptive statistics for cases and controls are presented in Table 1. Cases were older than controls and had lower educational achievement. Although this study was designed to match controls to cases by 5-year age group, the difference in the age at diagnosis/age at interview may, in part, be because the study is actively enrolling subjects. However, age ranges of cases (20–79 years) and controls (20–79 years) overlap. Significant differences in the distributions of well-established risk factors, including a shorter duration of oral contraceptive use, and lower prevalence of tubal ligation in cases as compared with controls, were as expected. As expected, parity was lower among cases compared with controls, but the difference was not significant. In addition, cases were more likely to report a family history of breast or ovarian cancer. No significant difference in the median years of use of body powder or occupational exposure of talc in cases compared with controls was observed.

Table 2 shows the results of logistic regression models examining the relationship between any use of body powder (either "only" nongenital powder or "any" genital powder) as well as the use of body powder by type of application: "only" nongenital powder use or "any" genital powder use. Adjusting for potential confounders, we observed a significant positive association between any powder use and EOC (OR = 1.39; 95% CI, 1.10–1.76). The OR for the association with "any" genital powder use was 1.44 (95% CI, 1.11–1.86). An OR of 1.31 (95% CI, 0.95–1.79) for the measure of association between "only" nongenital powder use and EOC was only slightly lower in magnitude compared with the association when "any" genital use was reported, but not statistically different from one another ($P = 0.56$). In 2014 and later, we observed an increase in any powder use of 12% and 6% of cases and controls, respectively. Although increased, these exposure prevalences were not significantly different from those interviewed before 2014 ($P = 0.30$). For those interviewed in 2014 or later, we observed an OR for "any" genital powder use of 2.91 (95% CI, 1.70–4.97) compared with 1.19 (95% CI, 0.87–1.63) before 2014. We observed a weaker OR of 1.26 (95% CI, 0.69–2.32) for 2014 and later compared with 1.40 (95% CI, 0.96–2.03) before 2014 for those who reported "only" nongenital use. A test for effect modification by year of interview was statistically significant ($P = 0.005$).

The ORs for the association between daily use of powder for either "only" nongenital powder use (OR = 1.53; 95% CI, 1.00–2.35) or "any" genital powder use (OR = 1.71; 95% CI, 1.26–2.33) with EOC were larger in magnitude than ORs for less than daily use compared with never use but the test for trend was significant for only "any" genital powder use (Table 2). There is a

Table 1. Characteristics of ovarian cancer cases and controls in the African American Cancer Epidemiology Study (AACES)

	Cases (<i>n</i> = 584) <i>n</i> (%)	Controls (<i>n</i> = 745) <i>n</i> (%)	<i>P</i>
Age (years)			<0.01
<40	31 (5.3)	80 (10.7)	
40–59	299 (51.2)	398 (53.4)	
60+	254 (43.5)	267 (35.8)	
Range (years)	20–79	20–79	
Education			0.02
High school or less	262 (44.9)	278 (37.3)	
Some after high school training	145 (24.8)	210 (28.2)	
College or graduate degree	177 (30.3)	257 (34.5)	
Body mass index (kg/m ²)			0.09
<24.9 (under- and normal weight)	86 (14.7)	140 (18.8)	
25–29.9 (overweight)	148 (25.3)	197 (26.4)	
>30 (obese)	350 (59.9)	408 (54.8)	
Parity (# of live births)			0.06
0	105 (18.0)	96 (12.9)	
1	113 (19.4)	141 (18.9)	
2	136 (23.3)	198 (26.6)	
3+	230 (39.4)	311 (41.6)	
Tubal ligation			0.02
Yes	201 (34.4)	302 (40.5)	
No	383 (65.6)	443 (59.5)	
Oral contraceptive use			<0.01
Never	180 (30.8)	155 (20.8)	
<60 months	230 (39.4)	334 (44.8)	
>60 months	174 (29.8)	256 (34.4)	
First-degree family history of breast or ovarian cancer			<0.01
Yes	149 (25.5)	132 (17.7)	
No	435 (74.5)	613 (82.3)	
Menopausal status			0.31
Premenopausal	158 (27.2)	221 (29.7)	
Postmenopausal	423 (72.8)	522 (70.3)	
Hormone therapy			0.10
Ever use	118 (20.3)	125 (16.8)	
Never use	463 (79.7)	618 (83.2)	
Smoking			0.48
Ever	257 (44.0)	313 (42.0)	
Never	327 (56.0)	432 (58.0)	
Hysterectomy ^a			0.43
Yes	141 (24.1)	166 (22.3)	
No	443 (75.9)	579 (77.7)	
Body powder use (median years) ^b	20	20	0.48
Occupational talc exposure ^c			0.16
Yes	58 (10.8)	62 (8.5)	
No	477 (89.2)	667 (91.5)	
Histologic subtype ^d			
Serous	393 (73.2)		
Mucinous	24 (4.5)		
Endometrioid	72 (13.4)		
Clear cell	13 (2.4)		
Other	35 (6.5)		

^aDefined as hysterectomy 2 years prior to diagnosis for cases and 2 years prior to interview for controls.

^bAmong body powder ever users only.

^cData not available for participants who completed the short questionnaire (49 cases and 16 controls).

^dData missing on histologic subtype for 47 cases.

moderately stronger association for ≥ 20 years of "any" genital powder use (OR = 1.51; 95% CI, 1.11–2.06) compared with <20 years of use (OR = 1.33; 95% CI, 0.95–1.86; $P_{\text{trend}} = 0.02$). No dose–response with years of use was detected for "only" nongenital powder use. The ORs for the number of lifetime applications

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Table 2. Adjusted ORs for the associations between mode, frequency, and duration of body powder use and ovarian cancer in the AACES

Exposure	Cases (n = 584) n (%)	Controls (n = 745) n (%)	OR ^a (95% CI)
Body powder use			
Never use	217 (37.2)	351 (47.1)	1.00 (Referent)
Ever use	367 (62.8)	394 (52.9)	1.39 (1.10–1.76)
Body powder use by location			
Never use	217 (37.2)	351 (47.1)	1.00 (Referent)
Only nongenital use	119 (20.4)	140 (18.8)	1.31 (0.95–1.79)
Any genital use	248 (42.5)	254 (34.1)	1.44 (1.11–1.86)
Interview date <2014 (n = 351)		(n = 571)	
Never use	147 (41.9)	286 (48.4)	1.00 (Referent)
Only nongenital use	76 (21.7)	104 (17.6)	1.40 (0.96–2.03)
Any genital use	128 (36.5)	201 (34.0)	1.19 (0.87–1.63)
Interview date >2014 (n = 233)		(n = 154)	
Never use	70 (30.0)	65 (42.2)	1.00 (Referent)
Only nongenital use	43 (18.4)	36 (23.3)	1.26 (0.69–2.32)
Any genital use	120 (51.5)	53 (34.4)	2.91 (1.70–4.97)
Frequency of use			
Never use	217 (37.3)	351 (47.2)	1.00 (Referent)
Only nongenital use			
Less than daily	61 (10.5)	82 (11.0)	1.15 (0.78–1.71)
Daily	58 (10.0)	58 (7.8)	1.53 (1.00–2.35)
P _{trend}			0.09
Any genital use			
Less than daily	88 (15.1)	119 (16.0)	1.12 (0.80–1.58)
Daily	158 (27.2)	134 (18.0)	1.71 (1.26–2.33)
P _{trend}			<0.01
Duration of use			
Never use	217 (37.4)	351 (47.4)	1.00 (Referent)
Only nongenital use			
<20 years	59 (10.2)	68 (9.2)	1.37 (0.91–2.07)
>20 years	60 (10.3)	70 (9.5)	1.28 (0.85–1.93)
P _{trend}			0.13
Any genital use			
<20 years	101 (17.4)	118 (15.9)	1.33 (0.95–1.86)
>20 years	144 (24.8)	134 (18.1)	1.52 (1.11–2.07)
P _{trend}			0.02
Lifetime body powder applications			
Never use	217 (37.4)	351 (47.4)	1.00 (Referent)
Only nongenital use			
Below median (<3,600 applications)	60 (10.3)	72 (9.7)	1.35 (0.90–2.03)
Above median (>3,600 applications)	59 (10.2)	66 (8.9)	1.30 (0.86–1.97)
P _{trend}			0.14
Any genital use			
Below median (<3,600 applications)	92 (15.9)	119 (16.1)	1.16 (0.83–1.63)
Above median (>3,600 applications)	152 (26.2)	133 (17.9)	1.67 (1.23–2.26)
P _{trend}			<0.01

^aAdjusted for age at diagnosis/interview, study site, education, tubal ligation, parity, BMI, duration of OC use, first-degree family history of breast or ovarian cancer, and interview year.

of body powder at or above and below the median support a dose–response with "any" genital powder use ($P_{\text{trend}} < 0.01$) but not for nongenital powder use ($P_{\text{trend}} = 0.14$).

A report of any occupational talc exposure, for those completing the long baseline questionnaire, was found to be positively, but not statistically significantly, associated with EOC (OR = 1.31; 95% CI, 0.88–1.93; data not shown). Table 3 shows an OR of 1.38 (95% CI, 1.03–1.85) for the association in serous cases with "any" genital powder use. Among serous cases, the OR for "only" nongenital powder use was lower in

magnitude and not significant (OR = 1.10; 95% CI, 0.76–1.58). Compared with serous cases, larger and statistically significant ORs are found for the associations with type of powder application in nonserous EOC cases; ORs were 1.63 (95% CI, 1.04–2.55) and 2.28 (95% CI, 1.39–3.74), for "any" genital powder use and "only" nongenital powder use, respectively (Table 3). A comparison of adjusted odds ratios between serous and nonserous histologic subtypes and powder use, detected a difference in "only" nongenital powder use ($P = 0.008$), but did not detect significant differences in association for "any" genital powder use ($P = 0.50$).

The stratified results by menopausal status (Table 4) suggest differences in the association for exposure to "only" nongenital powder use among premenopausal where no association is seen for "only" nongenital powder use, whereas the association with the risk of EOC and "any" genital use is elevated. Among postmenopausal women, we observed positive associations of similar magnitude for both the association between EOC and "only" nongenital powder use (OR = 1.49; 95% CI, 1.04–2.15) and "any" genital powder use (OR = 1.41; CI, 1.03–1.92). However, tests of interaction indicate no evidence for interaction by menopausal status for either route of exposure. Among menopausal women, analyses stratified by HT use suggest a stronger association among users compared with nonusers of HT for both routes of applications, although we detected a borderline, nonsignificant interaction for the associations with "any" genital body powder by HT use ($P = 0.06$). The test for interaction for nongenital body powder by HT use was not significant ($P = 0.76$).

To further consider the underlying mechanism for the relationship between use of body powder and the risk of EOC, we calculated the association between both "only" nongenital powder use and "any" genital powder use and having an upper respiratory condition. Controlling for case–control status, age at diagnosis/interview, study site, education, smoking, and BMI, we found ORs of 1.35 (95% CI, 0.89–2.05) and 1.45 (95% CI, 1.03–2.05) for "only" nongenital and "any" genital powder use, respectively, in relation to a reported respiratory condition, respectively (data not shown). A nonsignificant, but elevated OR of 1.26 (95% CI, 0.77–2.06) was observed with occupational exposure to talc and respiratory conditions (data not shown).

Table 3. Adjusted ORs for the associations between talc use and serous/nonserous EOC

Histologic subtype ^a	Cases n (%)	Controls n (%)	OR ^b (95% CI)
Serous (n = 392)			
Never use	156 (39.8)	351 (47.1)	1.00 (Referent)
Only nongenital use	71 (18.1)	140 (18.8)	1.10 (0.76–1.58)
Any genital use	165 (42.1)	254 (34.1)	1.38 (1.03–1.85)
Nonserous (n = 144)			
Never use	44 (30.6)	351 (47.1)	1.00 (Referent)
Only nongenital use	42 (29.2)	140 (18.8)	2.28 (1.39–3.74)
Any genital use	58 (40.3)	254 (34.1)	1.63 (1.04–2.55)

^aTest for interaction for association with powder use by serous and nonserous histologic subtype and route of body powder exposure was $P = 0.008$ for "only" nongenital powder use and $P = 0.50$ for "any" genital powder use.

^bAdjusted for age at diagnosis/interview, study site, education, tubal ligation, parity, BMI, duration of OC use, first-degree family history of breast or ovarian cancer, and interview year.

Table 4. Adjusted ORs for the association between EOC risk and body powder by menopausal status and HT use

Exposure	Premenopause			Postmenopause		
	Cases (n = 158) n (%)	Controls (n = 221) n (%)	OR ^a (95% CI)	Cases (n = 423) n (%)	Controls (n = 522) n (%)	OR ^a (95% CI)
Body powder use ^b						
Never use	59 (37.3)	103 (46.6)	1.00 (Referent)	157 (37.1)	247 (47.3)	1.00 (Referent)
Only nongenital use	22 (13.9)	42 (19.0)	0.90 (0.44–1.84)	97 (22.9)	98 (18.8)	1.49 (1.04–2.15)
Any genital use	77 (48.7)	76 (48.7)	1.50 (0.87–2.57)	169 (40.0)	177 (33.9)	1.41 (1.03–1.92)
HT ever/never use ^{c,d,e}						
HT ever use						
Never use				34 (32.1)	55 (48.7)	1.00 (Referent)
Only nongenital use				23 (21.7)	23 (20.4)	1.74 (0.77–3.92)
Any genital use				49 (46.2)	35 (31.0)	2.68 (1.33–5.40)
HT never use						
Never use				122 (38.9)	191 (46.9)	1.00 (Referent)
Only nongenital use				73 (23.3)	75 (18.4)	1.51 (0.99–2.29)
Any genital use				119 (37.9)	141 (34.6)	1.24 (0.87–1.79)

^aAdjusted for age at diagnosis/interview, study site, education, tubal ligation, parity, BMI, duration of OC use, first-degree family history of breast or ovarian cancer, and interview year.

^bTest for interaction between menopausal status and route of body powder exposure was nonsignificant for only non-genital use ($P = 0.21$) and any genital use ($P = 0.85$) compared with never use.

^cRestricted to postmenopausal women.

^dTest for interaction between HT use and only nongenital use was nonsignificant ($P = 0.76$).

^eTest for interaction between HT use and any genital use was nonsignificant ($P = 0.06$).

Discussion

In the largest EOC case-control study in AA women to date, we observed a positive association between regular use of powder and EOC regardless of the route of application. Users of genital powder were shown to have greater than a 40% increased risk of EOC compared with an increased risk of more than 30% among those who used only nongenital powder. The OR for the association with genital powder use in the current study is consistent with the association reported in AA women by Wu and colleagues (14). Of note, a high proportion of EOC cases (63%) and controls (53%) reported any use of body powder. A dose-response trend was evident for median years of use or greater as well as median number or greater of lifetime applications of "any" genital powder but not for use of "only" nongenital powder. Our results support that the association with "any" genital powder use is similar in premenopausal and postmenopausal women, whereas there appears to be an association with use of "only" nongenital powder use among postmenopausal but not premenopausal women. Associations were found among nonserous EOC cases and among postmenopausal users of HT exposed to either genital or nongenital powder.

Most previous case-control studies have not found an association between nongenital powder use and ovarian cancer, including a large pooled analysis by Terry and colleagues who reported an adjusted OR of 0.98 (95% CI, 0.89–1.07; refs. 6, 16). No prospective studies have evaluated nongenital powder use, nor has any study examined these associations by histologic subtype (17, 18). In the current study, the overall association with nongenital use and EOC was similar to that for genital powder use though it did not reach statistical significance possibly due to small numbers and random variation. However, we also did not find a dose-response relationship with frequency, duration, or lifetime applications of "only" nongenital powder use. Furthermore, we did not detect a significant association with use of "only" nongenital powder among serous cases, whereas the OR for the association with use of "only" nongenital powder showed over a 2-fold signif-

icant increased risk for nonserous EOC. In fact, we found a statistically significant difference between associations by subtype for "only" nongenital use. Given the inconsistency with previous published findings, it is also reasonable that under-reporting genital powder use, such as abdominal powder use that reaches the genital area, may have led to a spurious result. Another possible explanation for our finding may be that there is a higher inflammatory response in AAs compared with whites (23–25). Our results also suggest that the route of powder exposure may have different effects by histologic subtype. As most high-grade serous EOC, but not nonserous subtypes, arise in the fallopian tubes (26), it is possible that direct exposure through the genital tract specifically affects this disease subtype. The association with any genital powder use and nonserous cases may be due to the overlap between genital and nongenital powder use (83% of cases and 83% of controls). We were unable to examine associations with "only" genital powder users due to sample size considerations. In contrast, nongenital powder use may be related to inhalation of the exposure through the lungs. Several large pooled analyses have demonstrated risk factor associations with inflammatory-associated exposures, such as smoking (27), endometriosis (28), and obesity (29) with nonserous histologic subtypes of ovarian cancer but not high-grade serous EOC, providing a plausible theoretical basis for differences we found in associations by histologic subtype.

Akin to talc powders, titanium dioxide (TiO₂) is another inert particle that induces an inflammatory response upon inhalation and has been considered to be "possibly carcinogenic to humans" by IARC (2). Experimental evidence of enhanced inflammation due to exposure to inert environmental particulates of TiO₂ showed inhibition of phagocytic activity of alveolar macrophages in pregnancy, and was found to be associated with increased asthma risk in the offspring of BALB/c mice exposed to TiO₂. In this study, elevated estrogen levels during pregnancy were found to contribute to the resulting asthma risk (20). Our findings also support that enhanced airway inflammation is due to exposure to inert particles.

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Consistent with a recent study (15) where an association with powder use and asthma was reported, the relationship between body powder use and respiratory conditions likely reflects an enhanced inflammatory response due to powder use, suggesting a mechanism by which EOC risk is increased. Therefore, lung inhalation of powder could be a biologically plausible mechanism for the association between nongenital body powder use and increased EOC risk, particularly in nonserous EOC cases.

To further explore whether estrogen influences the inflammatory response, we performed stratified analyses by menopausal status. We did not see a difference in the association with premenopausal compared with postmenopausal use of "any" genital powder use, which is not consistent with a recent report (15) where an association with premenopausal use but not postmenopausal use was found. However, consistent with this report, we found a stronger association between "any" genital powder use and EOC among postmenopausal women who reported HT use compared with nonusers. This finding is also consistent with experimental data showing that in the presence of estrogen and/or estrogen and progesterone, the ability of macrophages to clear inert particulates is altered, enhancing the inflammatory response leading to the development of asthma in mouse offspring (20). It has also been proposed that chronic inflammation, resulting from exposure to body powder, whether through inhalation or through a transvaginal route, may exert a suppressive effect on adaptive immunity, leading to increased risk of EOC (30). These findings suggest that AA women may be particularly susceptible to exposure to body powder due to having higher endogenous estrogen levels compared with white women (31, 32). Because of the limited sample size, we were not able to evaluate associations with the timing or duration of HT use or the concurrent effects of both HT and powder use. Tests for interaction of the associations in the stratified analyses by HT use were not significant and our findings should be considered exploratory.

The results of the current study showed that genital powder use was associated with ovarian cancer risk in AA women and are consistent with localized chronic inflammation in the ovary due to particulates that travel through a direct transvaginal route. The dose-response observed for duration of genital powder use provides further evidence for the relationship between genital powder and overall EOC risk. Our data suggest that the increased risk due to use of genital powder applies to both serous and nonserous histologic subtypes of EOC. Use of "only" nongenital powder was not found to be associated with the serous subtype, but our data suggest a relationship with nonserous EOC. The association with serous EOC is consistent with several previous studies (4, 6, 14–17). Only the pooled analysis found associations with the endometrioid and clear cell subtypes (6). The association with any occupational talc exposure and EOC (OR = 1.31; data not shown), though not statistically significant, is also consistent with the results for "only" nongenital powder use and suggest other routes of exposure, aside transvaginal, may effect EOC risk.

A recent publication of data from the WHI, which did not find an association with genital talc use and ovarian cancer (18), was accompanied by an editorial that emphasized the challenges in assessing the exposure to talc due to the reliance on self-report (33). This limitation in the measurement of the exposure variables in the current study needs to be considered when interpreting our results. The possibility of differential misclassification exists in a

case-control study such as AACES, especially due to heightened awareness of the exposure as a result of two recent class action lawsuits (21). Because of such publicity, we adjusted for date of interview in the analysis. However, there is still a possibility that recall bias may have caused some inflation of the ORs. Although our findings suggest that the publicity of the class action lawsuits may have resulted in increased reporting of body powder use, our data do not support that recall bias alone before 2014 versus 2014 or later would account for the associations with body powder use and EOC. It is possible that the lawsuits sharpened memories of body powder use and improved the accuracy of reported use for both cases and controls interviewed in 2014 or later. As the association with nongenital body powder use is not consistent with the published literature, the possibility of misclassification of exposure, residual confounding, or a chance finding cannot be ruled out as an explanation for the associations with nongenital powder use.

In summary, we found that the application of genital powder is associated with serous and nonserous EOC in AA women, a novel observation in this population that is consistent with some large studies in whites. Our data are consistent with the notion that localized chronic inflammation in the ovary caused by exposure to genital powder contributes to the development of EOC. Although associations with nongenital powder use and EOC have not been previously reported, we cannot rule out the possibility that this relationship may be specific to AA women. The high prevalence of exposure to both genital and nongenital body powder among AA women compared with the mostly white subjects (41%), as in the large pooled analysis (6), underscores the importance of the study's findings. The results of the current study suggest that the use of body powder is an especially important modifiable risk factor for EOC in AA women.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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Cancer Epidemiology, Biomarkers & Prevention

Association between Body Powder Use and Ovarian Cancer: The African American Cancer Epidemiology Study (AACES)

Joellen M. Schildkraut, Sarah E. Abbott, Anthony J. Alberg, et al.

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Exhibit 25

Patricia G. Moorman, M.S.P.H., Ph.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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IN RE: JOHNSON & JOHNSON

TALCUM POWDER PRODUCTS	MDL No.:
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AND PRODUCTS LIABILITY	16-2738 (FLW)(LHG)
LITIGATION	

THIS DOCUMENT RELATES TO
ALL CASES

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VIDEOTAPED DEPOSITION OF
PATRICIA G. MOORMAN, M.S.P.H., PH.D.

FRIDAY, JANUARY 25, 2019

9:04 A.M.

Taken by the Defendants
at Cambria Hotel & Suites Durham
2306 Elba Street
Durham, North Carolina 27705

- - -

Reported by Sophie Brock, RPR, RMR, RDR, CRR

- - -

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<p>1 A. That's correct.</p> <p>2 Q. You were deposed in the Ingham case.</p> <p>3 Do you recall the name of the case?</p> <p>4 A. Yes, I do.</p> <p>5 Q. And you were last deposed in that case in</p> <p>6 March of 2018. Do you recall that?</p> <p>7 A. Yes, I do.</p> <p>8 Q. Has there been any change in your employment</p> <p>9 status since your March 2018 deposition?</p> <p>10 A. I am still a professor at Duke University,</p> <p>11 yes.</p> <p>12 Q. Has there been any change in your work or</p> <p>13 teaching activities since your deposition?</p> <p>14 A. Yes.</p> <p>15 Q. What are those changes?</p> <p>16 A. I am in a preretirement transition, and so</p> <p>17 I have been reducing my effort. And so I do not --</p> <p>18 I'm not doing as much teaching as I was a year ago.</p> <p>19 Q. Other than that fairly significant change,</p> <p>20 are there any other changes in your teaching or work</p> <p>21 activities since the deposition?</p> <p>22 A. No.</p> <p>23 Q. Have you done any new expert witness work</p> <p>24 since the last deposition other than the talc MDL that</p> <p>25 we're here about today?</p>	<p>1 A. I'm afraid I'm a little bit unclear about the</p> <p>2 particular cases. I understand that this is an MDL</p> <p>3 case. I have been in touch with attorneys about</p> <p>4 various cases since, you know, 2016, but I'm a little</p> <p>5 bit unclear about the distinctions.</p> <p>6 Q. In preparing for today's deposition for the</p> <p>7 talc MDL, did you meet with counsel?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And who did you meet with?</p> <p>10 A. I have met with the individuals here,</p> <p>11 Michelle Parfitt, Steve Faries, Alastair, and -- I'm</p> <p>12 blanking on his last name all of a sudden -- and Jeff</p> <p>13 Gibson.</p> <p>14 Q. Are those the only attorneys that you've met</p> <p>15 with regard to your deposition today?</p> <p>16 A. Yes.</p> <p>17 Q. In preparing your MDL talc report, are there</p> <p>18 any other attorneys that you worked with other than</p> <p>19 the ones that you just mentioned with regard to the</p> <p>20 MDL?</p> <p>21 MS. PARFITT: Objection. Form.</p> <p>22 You may answer.</p> <p>23 I just wanted to make sure that -- I believe</p> <p>24 he's asking the names of people, not the</p> <p>25 communications.</p>
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<p>1 A. No, I have not.</p> <p>2 Q. And you understand that we are taking your</p> <p>3 deposition today in the talc MDL; correct?</p> <p>4 A. Yes.</p> <p>5 Q. Who first contacted you about serving as an</p> <p>6 expert in the talc MDL?</p> <p>7 A. It was -- let's see -- Jeff Gibson was the</p> <p>8 first person who contacted me about talc litigation.</p> <p>9 Q. When you say "talc litigation," are you</p> <p>10 referring to the Ingham case?</p> <p>11 A. I'm afraid that I'm a little unclear on --</p> <p>12 you know, there are multiple attorneys, multiple</p> <p>13 cases, and I don't know who was the Defendant and when</p> <p>14 he first approached me.</p> <p>15 Q. Understood.</p> <p>16 A. Or the Plaintiff, rather. I'm sorry.</p> <p>17 Q. Do you recall the time frame that Mr. Gibson</p> <p>18 contacted you?</p> <p>19 A. It was in summer of 2016.</p> <p>20 Q. Are you retained in any talc cases other than</p> <p>21 the talc MDL and the Ingham case?</p> <p>22 A. Not to my knowledge, no.</p> <p>23 Q. Sitting here today, do you have the ability</p> <p>24 to distinguish as to whether any attorney contacted</p> <p>25 you specifically about the talc MDL?</p>	<p>1 MR. JAMES: Yes.</p> <p>2 THE WITNESS: Okay. I believe that on</p> <p>3 teleconferences, Chris Tisi was also on one of the --</p> <p>4 at least one of the teleconferences, probably more</p> <p>5 than one.</p> <p>6 BY MR. JAMES:</p> <p>7 Q. Was Mr. Tisi involved in teleconferences</p> <p>8 pertaining to the report that you authored?</p> <p>9 A. Yes.</p> <p>10 Q. And, again, I'm not asking you about the</p> <p>11 substance of the communications, just the</p> <p>12 identification of the attorneys that you've worked</p> <p>13 with. Okay?</p> <p>14 A. Okay.</p> <p>15 Q. Are there any other attorneys that you've</p> <p>16 worked with on the MDL report?</p> <p>17 A. None that I recall.</p> <p>18 Q. Are you working with any of the counsel that</p> <p>19 you just identified on any other litigation or</p> <p>20 matters?</p> <p>21 A. No, I am not.</p> <p>22 Q. Okay. Today at the deposition, we'll follow</p> <p>23 the same ground rules as the Ingham deposition. So</p> <p>24 I know that you're familiar with them, but as a</p> <p>25 reminder, my questions will be verbal and I ask that</p>

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<p>1 your answers be verbal as well. Okay?</p> <p>2 A. Okay.</p> <p>3 Q. And that's so the court reporter can take</p> <p>4 down what you're saying and can take down what I'm</p> <p>5 saying as well.</p> <p>6 Also, Michelle has told you this, but</p> <p>7 anytime you need a break, just let us know and we'll</p> <p>8 be happy to accommodate you. Okay?</p> <p>9 A. Okay.</p> <p>10 Q. And if you have any -- if you have any -- let</p> <p>11 me rephrase that.</p> <p>12 If you don't understand any questions that</p> <p>13 I ask you, please ask me to rephrase. Okay?</p> <p>14 A. Okay.</p> <p>15 Q. Great.</p> <p>16 What are you charging Plaintiffs' counsels</p> <p>17 in the MDL?</p> <p>18 A. My rate is \$400 per hour.</p> <p>19 Q. How much have you invoiced in the MDL to</p> <p>20 date?</p> <p>21 A. For the MDL, I believe it is 21,000.</p> <p>22 Q. Okay. And prior -- sorry. Did I cut you</p> <p>23 off?</p> <p>24 A. No, you did not.</p> <p>25 Q. This morning, your counsel handed me a copy</p>	<p>1 MS. PARFITT: And I've just got to add</p> <p>2 some clarity to that.</p> <p>3 MR. JAMES: Sure.</p> <p>4 MS. PARFITT: There might be some</p> <p>5 overlap. I think that's the problem. There might</p> <p>6 just be some overlap.</p> <p>7 BY MR. JAMES:</p> <p>8 Q. Are there any invoices that you have prepared</p> <p>9 for your work in the talc litigation that you have not</p> <p>10 produced to us today in the MDL, be it Exhibit 1 or in</p> <p>11 your work in Ingham?</p> <p>12 A. These are the only invoices related to the</p> <p>13 talc litigation, period.</p> <p>14 Q. And do you have an estimate of -- when you</p> <p>15 say that these are the only invoices for the talc</p> <p>16 litigation -- and if these questions continue to be</p> <p>17 confusing, let me know -- but are there other invoices</p> <p>18 that you submitted in the Ingham case that are not</p> <p>19 part of Exhibit 1?</p> <p>20 A. No. These are all the invoices submitted.</p> <p>21 Q. We got there finally. Sorry about that.</p> <p>22 A. Okay.</p> <p>23 Q. Have you discussed your work in this</p> <p>24 litigation with any other experts who are working on</p> <p>25 behalf of the Plaintiffs?</p>
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<p>1 of the invoices that you furnished in the MDL, and I'm</p> <p>2 going to mark this as Exhibit No. 1.</p> <p>3 (Exhibit No. 1 was marked for identification.)</p> <p>4 BY MR. JAMES:</p> <p>5 Q. Exhibit No. 1 is containing four invoices.</p> <p>6 I'm going to hand those to you and ask you to confirm</p> <p>7 that those are the invoices that you have prepared for</p> <p>8 your work in the MDL.</p> <p>9 A. There are some for -- that work that was done</p> <p>10 with the Ingham case, and my understanding, that's not</p> <p>11 part of the MDL.</p> <p>12 Q. That's fair. Yes.</p> <p>13 A. Okay.</p> <p>14 Q. So are the invoices that I've handed you as</p> <p>15 part of Exhibit 1, are those the invoices related to</p> <p>16 the work that you've done on the MDL?</p> <p>17 A. I -- I'm sorry. I'm -- I'm trying to answer</p> <p>18 your question, but the ones for prior -- other than</p> <p>19 the Ashcraft & Gerel, my understanding was that these</p> <p>20 were for, like, the Ingham case and the state cases,</p> <p>21 not the MDL.</p> <p>22 Q. Okay. Let me ask it this way: Are these the</p> <p>23 invoices that you've submitted to Michelle Parfitt?</p> <p>24 A. They've been submitted to the people noted on</p> <p>25 there. So --</p>	<p>1 A. No. To my knowledge, I have not.</p> <p>2 Q. Have you had any emails or other</p> <p>3 communications with Plaintiffs' experts in the talc</p> <p>4 litigation?</p> <p>5 A. No, I have not.</p> <p>6 Q. And you recall giving your testimony in the</p> <p>7 Ingham case in March 2018; correct?</p> <p>8 A. Yes, I do.</p> <p>9 Q. After that testimony that you provided, you</p> <p>10 also had an opportunity to review that testimony;</p> <p>11 correct?</p> <p>12 A. I did.</p> <p>13 Q. And do you recall preparing a single</p> <p>14 correction to the Ingham transcript?</p> <p>15 A. Yes.</p> <p>16 Q. And so I have with me a copy of what we refer</p> <p>17 to as an errata sheet, which is the correction sheet</p> <p>18 that you signed in Ingham. I'm going to mark that as</p> <p>19 Exhibit No. 2. Okay?</p> <p>20 (Exhibit No. 2 was marked for identification.)</p> <p>21 BY MR. JAMES:</p> <p>22 Q. And the way that we're configured, there's</p> <p>23 some space between me and your counsel. So when</p> <p>24 I have exhibits, as I will throughout the day --</p> <p>25 we may have to figure out how to approach this, but I</p>

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<p>1 may hand them to you and ask that you hand them over 2 since we're all miked up. 3 Okay. And do you recognize your handwriting 4 on that Exhibit? 5 A. I do. 6 Q. Does that reflect the correction that you 7 made to your testimony? 8 A. Yes, it does. 9 Q. And if you flip over to the other side of 10 Exhibit 2, does that contain your signature? 11 A. Yes, it does. 12 Q. By signing that errata sheet, you confirmed 13 that the testimony that you gave in Ingham was true 14 and correct; correct? 15 A. Yes. 16 Q. Do you still stand behind the testimony that 17 you provided in Ingham today? 18 A. Yes, I do. 19 Q. Subject to the one correction that you made; 20 correct? 21 A. Yes, I do. 22 Q. Sitting here today, do you believe there are 23 any other changes or corrections that you need to make 24 to your testimony in Ingham? 25 A. I can't think of any, no.</p>	<p>1 A. I am. 2 Q. Okay. So for purposes of the record, this 3 morning, before the deposition, your counsel handed me 4 a copy of your updated CV. 5 Is that what you're looking at right now? 6 A. Yes, it is. 7 Q. Okay. I'm going to mark a copy of that as 8 Exhibit No. 3. 9 (Exhibit No. 3 was marked for identification.) 10 MR. JAMES: Michelle, you have a copy, 11 I presume? 12 MS. PARFITT: Actually, I think I gave 13 them all to you. Sorry. 14 MR. JAMES: Again, apologies for having 15 to handle it that way. 16 THE WITNESS: Oh, I'm sorry. 17 MS. PARFITT: Thank you. 18 THE WITNESS: Okay. The article that 19 I was referring to is -- the first author is Park. 20 The title of the article is "Benign gynecologic 21 conditions are associated with ovarian cancer risk in 22 African-American women: A case-control study." 23 And I was a coauthor on that paper, and talc 24 was included as a potential confounder. 25</p>
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<p>1 Q. Did you review your Ingham deposition in 2 preparation for today's deposition? 3 A. I did within the last few weeks, yes. 4 Q. And so when you've reread the transcript in 5 the last few weeks, did you see anything in that 6 transcript that you wanted to correct? 7 A. No. 8 Q. Since your Ingham deposition in March of 9 2018, have you authored any publications or articles 10 pertaining to talc, asbestos, or ovarian cancer risk 11 factors? 12 A. Yes, I have. 13 Q. Okay. And let's break up that, then. 14 Have you authored any articles pertaining to 15 talc? 16 A. I have not authored any articles that 17 directly address talc as the main focus of the paper. 18 Talc has been mentioned in at least one paper as a 19 potential confounder. 20 Q. And what was the name of that article, 21 please. 22 A. If you'll give me just a moment, let me 23 look -- 24 Q. Dr. Moorman, are you looking at a copy of 25 your CV?</p>	<p>1 BY MR. JAMES: 2 Q. And, for the record, can you tell us the 3 number of the item you're looking at on your CV? 4 A. Okay. On page 14, it is Article No. 120. 5 Q. And in that paper, Dr. Moorman, did you say 6 that you described talc as a potential confounder? 7 A. Yes. 8 Q. In that paper, did you include a disclosure 9 of your involvement in this talc litigation as an 10 expert for the Plaintiffs? 11 A. I disclosed it -- actually, I had a 12 discussion with the senior author on this paper, who's 13 Michele Cote, and disclosed what I was doing. And she 14 was -- she actually said she had also done some work 15 related to talc and ovarian cancer and she was going 16 to check with the editor and see if it required a 17 disclosure. And so there was no disclosure. So 18 apparently the editor did not feel it was warranted. 19 Q. So the article, as published, does not 20 contain a disclosure of your involvement in the 21 litigation; correct? 22 A. That is correct. 23 Q. Did you review the disclosure requirements of 24 the journal in which the article was published? 25 A. I can't remember if I specifically looked at</p>

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<p>1 that journal's requirements. I don't recall if I did 2 or not.</p> <p>3 Q. Do you believe that it is important -- for an 4 author who's working on an article for a publication 5 pertaining to an issue that she's testifying about in 6 litigation, do you believe it's important to disclose 7 that to the reader of the article?</p> <p>8 A. I think that it is important to disclose it 9 in conjunction with the journal's policies, as I 10 described. I did disclose it to the corresponding 11 author, who said she was going to discuss it with the 12 editor. So I think that I did what was appropriate.</p> <p>13 Q. Did you communicate your involvement in the 14 litigation to anyone with the journal?</p> <p>15 A. I did not. It is typical that the 16 communication with the journal is through the 17 corresponding author.</p> <p>18 Q. Have you attempted to amend any disclosures 19 in your prior papers since the last deposition?</p> <p>20 MS. PARFITT: Objection. Form.</p> <p>21 THE WITNESS: I do --</p> <p>22 MR. JAMES: You're looking at your 23 counsel. Michelle can correct me if I'm wrong. She's 24 allowed to make the objections. And once she does, 25 unless she tells you not to answer, you may answer.</p>	<p>1 Q. Did they communicate with you about the 2 disclosure in a written format?</p> <p>3 A. It was an email communication.</p> <p>4 Q. Was it a single email, or was it multiple 5 emails?</p> <p>6 A. As I recall, I sent an email to the editor 7 disclosing the situation, and he -- I think he 8 responded that, yes, it should be disclosed. And then 9 I believe there was another email from -- I don't 10 know -- an editorial assistant or someone asking 11 specifically what was the -- what was the wording of 12 the disclosure that I wanted to make, and I gave them 13 that.</p> <p>14 So it was, you know, two or three emails, 15 but...</p> <p>16 Q. Do you still have that email traffic in your 17 possession?</p> <p>18 A. Probably.</p> <p>19 Q. It's on your computer?</p> <p>20 A. I would think so.</p> <p>21 Q. Okay. Could you ensure that you preserve 22 that email traffic for us, please.</p> <p>23 A. Yes.</p> <p>24 MR. JAMES: And then, Michelle, we will 25 request a copy of the email traffic.</p>
Page 23	Page 25
<p>1 MS. PARFITT: That's fine.</p> <p>2 THE WITNESS: Okay. Yes. In my last 3 deposition, there was an article that I was one of 40 4 authors that looked at about 20 different risk factors 5 for ovarian cancer. I acknowledged in my deposition 6 that it was an oversight. In my career, you know, 7 spanning 25 years, I've never had to make disclosures 8 about potential conflicts of interest. I acknowledged 9 that it was an oversight on my part. When it was 10 brought to my attention, I contacted the journal, and 11 they said, "Okay. What's your disclosure?" And 12 I disclosed it.</p> <p>13 BY MR. JAMES:</p> <p>14 Q. So just to be clear, this was after the 15 deposition; correct?</p> <p>16 A. It was.</p> <p>17 Q. Is this the Peres paper?</p> <p>18 A. Yes.</p> <p>19 Q. Did they respond to you in any way about the 20 reported conflict?</p> <p>21 A. The editor just said, "Okay. What is your 22 disclosure?"</p> <p>23 And I gave it to him. And I believe that 24 they subsequently published a correction to the 25 article.</p>	<p>1 MS. PARFITT: We'll certainly take it 2 under advisement, sure.</p> <p>3 BY MR. JAMES:</p> <p>4 Q. Do you have any similar written 5 communications about the disclosure with the paper 6 that we just discussed, the Park paper?</p> <p>7 A. No, I do not. That was a telephone 8 conference.</p> <p>9 Q. Other than the Park article that you just 10 identified, have you authored any other articles since 11 your last deposition concerning talc, asbestos, or 12 risk factors for ovarian cancer?</p> <p>13 A. As you can see on my CV, since the last 14 deposition, Article No. 121 is a paper on effect of 15 cultural, folk, and religious beliefs on delays in 16 diagnosis of ovarian cancer. I was first author on 17 that paper.</p> <p>18 Article 119, first author Anderson, was 19 looking at individual, social, and societal correlates 20 of health-related quality of life among 21 African-American survivors of ovarian cancer.</p> <p>22 And I was a coauthor on a paper by Mills 23 that was looking at immune regulatory molecular 24 expression.</p> <p>25 Q. Since your Ingham deposition, have you</p>

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<p>1 authored any articles that pertain to talc or asbestos 2 other than the Park article? 3 A. No. 4 Q. Are you currently working on any articles or 5 publications that pertain to the issues addressed in 6 your expert report? 7 A. I am a coauthor on a paper that is in 8 preparation that is describing the OCWAA Consortium, 9 which stands for Ovarian Cancer in Women of African 10 Ancestry. And this is a relatively newly formed 11 consortium, and it's describing the overall structure 12 of the consortium and some of the factors that we 13 intend to consider. And in the draft of the paper, 14 talc is included along with a long list of other risk 15 factors that we will be considering. 16 Q. Is that paper in draft form? 17 A. It is in draft form. It's being -- yeah, it 18 has not been submitted yet. 19 Q. So it has not been submitted for peer review? 20 A. No, it has not. 21 Q. Is talc mentioned in the context of a 22 potential confounder, like the Park paper? 23 MS. PARFITT: Object to form. 24 THE WITNESS: Talc is mentioned in that 25 paper as one of many ovarian cancer risk factors that</p>	<p>1 communications or written paperwork about your 2 conflict for that paper? Your litigation disclosure 3 for that paper? Is there anything in writing about 4 that to anyone or the journal itself, or a journal? 5 A. At this point, no, because it is still in 6 draft form. It's not ready to be submitted. 7 Q. Okay. Other than the papers we have 8 discussed this morning, are there any other papers 9 that you -- that are works in progress that discuss 10 talc or asbestos that you're working on? 11 A. Another paper that is in progress is looking 12 at infertility as a risk factor for ovarian cancer. 13 And talc is, again, considered as a potential 14 confounder of that association. 15 So, again, draft form. It hasn't been 16 disclosed yet because it's not at the point where one 17 would disclose that. 18 Q. Okay. And you answered my next question, and 19 that's fine. So thank you. 20 Can you identify the coauthors on the paper 21 that you've just -- that you just mentioned, the 22 infertility paper? 23 A. The infertility paper? Okay. This was work 24 that was done with a medical student, Tolu Teniola is 25 the medical student that I was working with. And then</p>
Page 27	Page 29
<p>1 we hope to examine in this -- within this consortium. 2 BY MR. JAMES: 3 Q. So one of the purposes of that paper, as 4 you've described, is that you will be looking at the 5 association between talc and ovarian cancer; is that 6 correct? 7 MS. PARFITT: Objection. Form. 8 THE WITNESS: It is -- the purpose of 9 the paper is to describe the consortium. So there is 10 relatively little data about risk factors for ovarian 11 cancer among African -- African-American women, or 12 women of African ancestry. And so the purpose of the 13 paper is not focused just on talc, but it is 14 describing how the consortium hopes to compare risk 15 factors for ovarian cancer between African-American 16 and white women. So talc is among a long list of risk 17 factors that will be considered as we progress with 18 this consortium. 19 BY MR. JAMES: 20 Q. Have you yet disclosed your involvement in 21 the litigation with respect to that paper? 22 A. The -- I will disclose it when the paper will 23 be submitted, which is the typical time when such a 24 disclosure would be made. 25 Q. Have you engaged in any written</p>	<p>1 all of the AACES -- this is, again, African American 2 Cancer Epidemiology Study, which is an ovarian cancer 3 study that I've worked on for about the last nine or 4 ten years, and so all of the collaborators on that 5 study. 6 And when you look at the CV, the papers that 7 come from AACES, it's Dr. Schildkraut, Dr. Bondy, 8 Dr. Cote. It's a large multicenter study; there are 9 many coauthors, and so they would all be included. 10 Q. And with respect to the other 11 work-in-progress paper that you have identified, can 12 you identify the coauthors on that paper. 13 MS. PARFITT: Are you speaking of the 14 infertility paper? 15 MR. JAMES: The first question was 16 about the infertility. So now we're back to the first 17 work-in-progress paper that you identified. 18 THE WITNESS: Okay. So the study 19 describing the OCWAA Consortium, is that what you're 20 asking me about? 21 BY MR. JAMES: 22 Q. Yes, Doctor. Thank you for clearing that up. 23 A. Okay. So it includes -- again, this is a 24 multicenter study -- quite a few coauthors. They 25 would include Dr. Schildkraut, Lynn Rosenberg, Traci</p>

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<p>1 Bethea, Wendy Setiawan.</p> <p>2 Again, it's a large consortium with a lot of</p> <p>3 coauthors. There would be probably at least a dozen,</p> <p>4 probably more.</p> <p>5 Q. For both work-in-progress papers, are you</p> <p>6 aware of whether any of those coauthors are experts</p> <p>7 for the Plaintiffs in the talc litigation?</p> <p>8 A. I am not aware of -- if any of them are.</p> <p>9 Q. Have you -- are there any other works in</p> <p>10 progress that pertain to talc or asbestos that you're</p> <p>11 working on?</p> <p>12 A. No, I do not believe so.</p> <p>13 Q. Have you submitted the substance of your</p> <p>14 opinions in the MDL report to anyone for peer review?</p> <p>15 A. No, I have not.</p> <p>16 Q. Have you engaged in any internet postings,</p> <p>17 blogs, chatroom postings concerning your opinions in</p> <p>18 this litigation?</p> <p>19 A. No, I have not.</p> <p>20 Q. Have you given any presentations, speeches,</p> <p>21 or lectures concerning talc or asbestos or ovarian</p> <p>22 cancer risk factors since your March 2018 deposition?</p> <p>23 A. No, I have not.</p> <p>24 Q. Have you given any interviews, public</p> <p>25 statements, or other public speaking engagements</p>	<p>1 communications with your professional colleagues about</p> <p>2 your opinions?</p> <p>3 A. No, I have not.</p> <p>4 Q. And when I say "about your opinions," I mean</p> <p>5 about your opinions in this litigation.</p> <p>6 Is there any written communications, emails,</p> <p>7 or other writings expressing your opinions in this</p> <p>8 litigation to your professional colleagues?</p> <p>9 A. No, I do not believe so.</p> <p>10 Q. Have you had any discussions, since your</p> <p>11 Ingham deposition, with any healthcare professionals</p> <p>12 who treat ovarian cancer patients about your</p> <p>13 litigation opinions?</p> <p>14 A. No, I have not.</p> <p>15 Q. Have you prepared any letters to the editor</p> <p>16 about any of the publications that you cite in your</p> <p>17 MDL report?</p> <p>18 A. No, I have not.</p> <p>19 Q. Okay. I am going to hand you a copy of the</p> <p>20 deposition notice for this case. I'm going to mark</p> <p>21 that as Exhibit No. 4.</p> <p>22 (Exhibit No. 4 was marked for identification.)</p> <p>23 MR. JAMES: Michelle, do you need a</p> <p>24 copy?</p> <p>25 MS. PARFITT: I believe I might have</p>
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<p>1 concerning talc, asbestos, or ovarian cancer risk</p> <p>2 factors since your Ingham deposition?</p> <p>3 A. No, I have not.</p> <p>4 Q. Since your Ingham deposition -- and I'm</p> <p>5 structuring my questions sometimes this way in hopes</p> <p>6 of expediting. Okay?</p> <p>7 So since your Ingham deposition, have you</p> <p>8 discussed your opinions in this litigation with any of</p> <p>9 your professional colleagues?</p> <p>10 A. To some extent, yes.</p> <p>11 Q. Okay. And can you tell me who that is?</p> <p>12 A. I already mentioned Dr. Cote, Michele Cote,</p> <p>13 described the work that I was doing.</p> <p>14 I have mentioned some of the work that I'm</p> <p>15 doing to some of my colleagues within my department,</p> <p>16 Dr. Truls Ostbye for one, Dr. Kat Pollak for another.</p> <p>17 Q. And when you say that you've mentioned your</p> <p>18 litigation work with your department colleagues, what</p> <p>19 have you told them?</p> <p>20 A. I have basically described that I have been</p> <p>21 working as an expert witness in this -- in this case,</p> <p>22 and expressing my opinion, you know, that -- working</p> <p>23 for the Plaintiffs and my opinion that talc is a cause</p> <p>24 of ovarian cancer.</p> <p>25 Q. And have you engaged in any written</p>	<p>1 given you mine. If you would be so kind, I appreciate</p> <p>2 that.</p> <p>3 MR. JAMES: Dr. Moorman.</p> <p>4 THE WITNESS: Thank you.</p> <p>5 BY MR. JAMES:</p> <p>6 Q. Okay. Dr. Moorman, have you seen the</p> <p>7 deposition notice that I just handed you before?</p> <p>8 A. Yes, I have.</p> <p>9 Q. Okay. And you understand from your prior</p> <p>10 deposition, that this is a document that formally</p> <p>11 notices the time and place and why we're here; right?</p> <p>12 A. Yes.</p> <p>13 Q. And if you turn to page 3 of the notice, you</p> <p>14 see that there is a section for definitions, and then</p> <p>15 it follows with a list of document requests; correct?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And your counsel this morning has</p> <p>18 produced to me a copy of your invoices, a copy of your</p> <p>19 updated CV, an additional-materials-considered list,</p> <p>20 and has also indicated that the references to your MDL</p> <p>21 report are going to be available to us on a thumb</p> <p>22 drive.</p> <p>23 Other than those materials that I just</p> <p>24 described, are there any other materials that you've</p> <p>25 brought with you today that respond to this deposition</p>

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<p>1 notice?</p> <p>2 A. No, there are no other documents.</p> <p>3 MR. JAMES: Michelle, is there anything</p> <p>4 else that you brought with you that is responsive to</p> <p>5 the deposition notice?</p> <p>6 MS. PARFITT: You know, the only thing</p> <p>7 that might -- I believe you asked this, Mr. James --</p> <p>8 any notes that she might have taken.</p> <p>9 MR. JAMES: Yes, I was going to ask</p> <p>10 that.</p> <p>11 MS. PARFITT: So why don't we just wait</p> <p>12 for that. I do have something for that.</p> <p>13 MR. JAMES: Okay. Fair enough.</p> <p>14 BY MR. JAMES:</p> <p>15 Q. Dr. Moorman, did you provide to your counsel</p> <p>16 any working copies of materials that you've reviewed</p> <p>17 for purposes of preparing your report or preparing for</p> <p>18 today's deposition?</p> <p>19 A. Can you tell me what you mean by "working</p> <p>20 copies"?</p> <p>21 Q. Sure. Have you made any notes on any of the</p> <p>22 materials that you reviewed for purposes of your work</p> <p>23 on the MDL?</p> <p>24 A. Yes. In this notebook here, there are</p> <p>25 articles. Most of them are the epidemiologic studies.</p>	<p>1 in your possession that are not contained in this</p> <p>2 binder?</p> <p>3 A. No. It's there and the report. That's it.</p> <p>4 MS. PARFITT: Mr. James, if we could,</p> <p>5 do you mind, could she have that back? In the event</p> <p>6 you start to ask her questions about it, she may want</p> <p>7 hers instead, and then we'll make sure you get it.</p> <p>8 Thank you.</p> <p>9 BY MR. JAMES:</p> <p>10 Q. And before we commenced this morning, your</p> <p>11 counsel, Ms. Parfitt, handed me a copy of the</p> <p>12 objections that they have lodged -- that the</p> <p>13 Plaintiffs have lodged to the deposition.</p> <p>14 MR. JAMES: Ms. Parfitt, do you want to</p> <p>15 mention that on the record?</p> <p>16 MS. PARFITT: Yes. If we could kindly</p> <p>17 have marked as Exhibit No. -- I believe it's 6 now.</p> <p>18 This is the Plaintiffs Steering Committee's Response</p> <p>19 and Objections to the Oral and Video Deposition of</p> <p>20 Dr. Patricia Moorman.</p> <p>21 Thank you.</p> <p>22 (Exhibit No. 6 was marked for identification.)</p> <p>23 BY MR. JAMES:</p> <p>24 Q. Dr. Moorman, I'm just going to hand you a</p> <p>25 copy of this because it looks like you're keeping a</p>
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<p>1 And on some of them, I have notes that basically help</p> <p>2 me kind of categorize and -- categorize the articles</p> <p>3 and some of the main things that they looked at. You</p> <p>4 know, did they address dose-response? Did they look</p> <p>5 at histology? Those types of things. It was just to</p> <p>6 kind of help me sort them out.</p> <p>7 Q. And you brought that binder with you here</p> <p>8 today; correct?</p> <p>9 A. Correct.</p> <p>10 MR. JAMES: Michelle, I'm going to mark</p> <p>11 that as Exhibit No. 5.</p> <p>12 MS. PARFITT: You can. What I would</p> <p>13 ask, last evening we didn't have the ability to get</p> <p>14 everything copied. So what we will do is, we can mark</p> <p>15 that, and we'll make some arrangements to get that</p> <p>16 copied so we can get the originals back to</p> <p>17 Dr. Moorman.</p> <p>18 MR. JAMES: Sure. That's fine.</p> <p>19 So I'm going to mark this binder</p> <p>20 Exhibit No. 5.</p> <p>21 (Exhibit No. 5 was marked for identification.)</p> <p>22 BY MR. JAMES:</p> <p>23 Q. Dr. Moorman, other than what you've provided</p> <p>24 to me in Exhibit No. 5, are there any other notes or</p> <p>25 working copies of materials considered that you have</p>	<p>1 pile over there for us of all the exhibits. Okay?</p> <p>2 I'm not going to ask any questions about it.</p> <p>3 A. Okay.</p> <p>4 Q. Okay. Dr. Moorman, in anticipation -- or in</p> <p>5 preparation for your work on the MDL, or in</p> <p>6 conjunction with your work on the MDL, you also</p> <p>7 authored an expert report; correct?</p> <p>8 A. That is correct.</p> <p>9 Q. I'm going to mark a copy of that as</p> <p>10 Exhibit No. 7. And we'll be talking about this</p> <p>11 throughout the day today. Okay?</p> <p>12 A. Okay.</p> <p>13 (Exhibit No. 7 was marked for identification.)</p> <p>14 Q. Okay. I'm handing you Exhibit 7. Is that a</p> <p>15 copy of your report that you've authored in the MDL?</p> <p>16 A. Yes, it is.</p> <p>17 Q. Do you agree that the report defines the</p> <p>18 scope of the opinions that you intend to offer in the</p> <p>19 MDL?</p> <p>20 A. Yes.</p> <p>21 MS. PARFITT: If I may, Scott, may</p> <p>22 I just see a copy of that report?</p> <p>23 MR. JAMES: I have extra copies as</p> <p>24 well, Michelle. If you need anything, just let me</p> <p>25 know.</p>

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<p>1 MS. PARFITT: Thank you. That would be 2 great. 3 MR. FARIES: I'll be the runner on this 4 one. 5 MR. JAMES: Thank you. 6 BY MR. JAMES: 7 Q. Did you review your report prior to -- in 8 preparation -- let me start that over. 9 Did you review your report in preparation 10 for today's deposition? 11 A. Yes, I did. 12 Q. Are there any changes that you want to make 13 to the report today? 14 A. No, there are not. 15 Q. Did you write the report? 16 A. Yes, I did. 17 Q. Okay. Are all parts of the report in your 18 wording? 19 A. Yes. 20 Q. Okay. If you can turn with me, Dr. Moorman, 21 to page 41. And you see here that there is a list of 22 references; correct? 23 A. Yes. 24 Q. Okay. And if you also turn to page 50, do 25 you see that there's a separate list that begins on</p>	<p>1 transcript for Curtis Omiencinski, I do not recall 2 reviewing that at all. It might have been provided to 3 me, but I don't recall reviewing it. 4 Q. Is there any way sitting here today that we 5 can efficiently identify which items on the additional 6 materials list that you have reviewed and which you 7 haven't? 8 A. I don't know what you mean by "efficiently." 9 You know, it's kind of hard to recall exactly. You 10 know, there are lots of articles here. That might 11 have been provided to me. I don't know how I could go 12 through it in just a few minutes to say did I look at 13 it or not. It would just take some time. 14 Q. Did Plaintiffs' counsel provide you all the 15 items on this list, the additional materials list? 16 A. No, I don't believe so. I mean, some of the 17 articles I've had -- like, again, some of them just 18 kind of jump out at me, like the reference 31, 19 Fathalla, "Incessant ovulation and ovarian cancer, a 20 hypothesis," that is an article that I have probably 21 referred to dozens of times. 22 Q. So the additional materials list contains a 23 mixture of items that you had on your own and items 24 that were provided to you; is that fair? 25 A. That is correct.</p>
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<p>1 page 50, halfway down, that's titled "Additional 2 materials and data considered"? 3 A. I'm sorry -- 4 Q. On page 50. 5 A. -- let me get to the right page. 6 Yes. 7 Q. Can you explain to me the difference between 8 the reference list and the additional materials and 9 data considered list? 10 A. Okay. The reference list are the references 11 to support the opinions and the statements in the 12 report that I wrote. There are some other materials 13 that I was provided, might have read, but they just 14 did not meet the level of actually needing to be 15 referenced in the report to support a certain 16 statement. 17 Some of these I might have read in more 18 detail than others, but I feel like the reference list 19 are the ones that actually supported the statements 20 that I made in my report. 21 Q. As described by you just now, are there items 22 on the additional materials and data considered list 23 that you have not reviewed at all? 24 A. There are -- along the way, there seem to be 25 some -- like, for example, item 62, comparing a</p>	<p>1 Q. Now, do you intend to rely on any materials 2 for your opinions in this case that are not identified 3 in the reference list or the additional materials 4 list? 5 MS. PARFITT: Objection. Form. 6 THE WITNESS: I mean, I am relying on 7 the expertise that I developed over more than 25 years 8 as an epidemiologist. And so there may be 9 publications, knowledge that I have that is not 10 specifically listed here. But, in general, I think 11 that is a fairly comprehensive list. I don't know 12 that I could say that it is completely exhaustive. 13 BY MR. JAMES: 14 Q. All right. I'm going to mark now as 15 Exhibit No. 8 a copy of a list entitled "Additional 16 Materials to Dr. Patricia Moorman." 17 (Exhibit No. 8 was marked for identification.) 18 BY MR. JAMES: 19 Q. Have you seen a copy of Exhibit 8 before, 20 Dr. Moorman? 21 A. I don't think that I have seen this 22 particular list. 23 MS. PARFITT: And for the record, this 24 list was compiled by Plaintiffs' counsel, Mr. James, 25 and I'm not sure whether or not my office -- the</p>

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<p>1 materials were sent, but I'm not sure whether the list 2 was sent to Dr. Moorman. 3 MR. JAMES: Okay. 4 BY MR. JAMES: 5 Q. Looking at this list, Dr. Moorman, this list 6 was furnished to us this week. 7 Do you understand that? 8 MS. PARFITT: Objection. 9 THE WITNESS: I -- if you say so. 10 BY MR. JAMES: 11 Q. Fair enough. This list -- does this list 12 include items that you were provided after you 13 authored your MDL report? 14 A. Yes. 15 Q. This list of materials did not form the 16 opinions that you included in your MDL report; 17 correct? 18 MS. PARFITT: Objection. Form. 19 THE WITNESS: I did not have access, 20 you know, to these expert reports and all before 21 I wrote my report, no. So they did not inform my 22 report. 23 BY MR. JAMES: 24 Q. Have you reviewed the materials on this list 25 as Exhibit No. 8 in their entirety?</p>	<p>1 reports have you reviewed? 2 A. Again, I have reviewed them in different 3 levels of detail and completeness. But I have looked 4 at the report of Anne McTiernan, April 5 Zambelli-Weiner, Daniel Clarke-Pearson, David Kessler, 6 Jack Siemiatycki, Michael Crowley, Rebecca 7 Smith-Bindman, and Sonal Singh, you know, to some 8 extent. 9 And I might have looked at some of the 10 others, but those were the ones that I specifically 11 recall looking at to some extent. 12 Q. Did you ask for Plaintiffs' counsel to 13 furnish you the expert reports in the litigation? 14 A. I did not. They provided them to me without 15 asking. 16 Q. Why did you review the reports of the other 17 experts? 18 A. Intellectual curiosity is the main thing. 19 I'm always interested to learn other people's 20 perspectives. And also to see if there was any 21 additional evidence that I might consider. 22 Q. And after reviewing those reports, did you 23 find any additional evidence that you might consider 24 that you didn't list in your MDL report? 25 A. I really didn't. I thought that there was a</p>
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<p>1 A. No, not in their entirety. 2 Q. Have you reviewed some and not reviewed 3 others? Is that fair? 4 A. I have -- yes, I have reviewed some of them. 5 I have not reviewed all of them. 6 Q. Okay. Is there any way for us to, again, 7 efficiently determine today which of these you've 8 reviewed and which ones you haven't? 9 A. I -- again, I could go through them and, to 10 the best of my knowledge, tell you which ones 11 I reviewed. Again, some of them I reviewed in more 12 detail, read more completely; others I looked at 13 more -- in a more cursory way. 14 Q. Did your review of any of these additional 15 materials change the opinions that you've included in 16 your MDL report? 17 A. No, they did not change my opinion. 18 Q. Did you review all of these expert reports 19 listed? 20 A. I did not review all of them. I reviewed 21 some of them. 22 Q. Okay. And these are the Plaintiffs' expert 23 reports that are listed on this list; correct? 24 A. That is my understanding. 25 Q. Okay. Which of the Plaintiffs' expert</p>	<p>1 remarkable level of consistency in the opinions, 2 particularly among the people who were reviewing the 3 epidemiologic literature. 4 Q. Dr. Moorman, I am going to now hand you a 5 copy of the reliance materials -- which is the title 6 of the list -- that you cited in the Ingham case. 7 Okay? I'm going to mark that as Exhibit No. 9. 8 (Exhibit No. 9 was marked for identification.) 9 BY MR. JAMES: 10 Q. Does that list look familiar to you? 11 A. Yes. 12 Q. And you see on the front of that list, it 13 says it was produced on March 5th, 2018; correct? 14 A. That is correct. 15 Q. And did you prepare this list? 16 A. I did not personally prepare it, no. 17 Q. Do you know that the reliance list that you 18 produced in Ingham and the reliance list that you have 19 attached as a reference list and a materials 20 considered list to your MDL report are substantially 21 different? 22 A. I would -- 23 MS. PARFITT: Objection. Form. 24 THE WITNESS: I would not be surprised 25 to say that there are some different references cited,</p>

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<p>1 yes.</p> <p>2 BY MR. JAMES:</p> <p>3 Q. Do you understand that there's a large number</p> <p>4 of additional references that you have now cited in</p> <p>5 your MDL report?</p> <p>6 A. I -- the reference list is longer, yes.</p> <p>7 Q. Do you have any idea by how much?</p> <p>8 MS. PARFITT: Objection. Form.</p> <p>9 THE WITNESS: No, I do not.</p> <p>10 BY MR. JAMES:</p> <p>11 Q. Would it surprise you to find out that there</p> <p>12 are 94 new items listed in your MDL report that were</p> <p>13 not listed in your March 2018 report?</p> <p>14 MS. PARFITT: Objection. Form.</p> <p>15 THE WITNESS: I -- you know, as you go</p> <p>16 along, I think that it is not unusual to include more</p> <p>17 references. I didn't know the exact number of new</p> <p>18 items.</p> <p>19 BY MR. JAMES:</p> <p>20 Q. Again, did you prepare the lists that are</p> <p>21 attached to your MDL report?</p> <p>22 A. The -- the list of references, I prepared</p> <p>23 that. The list of additional items, I think that was</p> <p>24 a combination of some of what I had prepared and</p> <p>25 I think what counsel had provided to me.</p>	<p>1 have become part of the public domain since that time.</p> <p>2 Do you understand that?</p> <p>3 MS. PARFITT: Objection. Form.</p> <p>4 THE WITNESS: I understand that some of</p> <p>5 them had been published before my deposition in March</p> <p>6 2018.</p> <p>7 BY MR. JAMES:</p> <p>8 Q. Are there specific topics of the new</p> <p>9 materials that you added between your Ingham</p> <p>10 deposition and your MDL report?</p> <p>11 A. I'm trying to think what they might be. I --</p> <p>12 some -- I think that some of the work, for example, by</p> <p>13 Fletcher and Saed describing some of their work</p> <p>14 related to possible biological mechanisms by which</p> <p>15 talc exposure could lead to ovarian cancer -- I think</p> <p>16 that was some work that I, perhaps, had not been aware</p> <p>17 of previously. And so that's one thought that comes</p> <p>18 to mind.</p> <p>19 Q. All of the items that you added from March</p> <p>20 2018 Ingham list to your MDL list, were all of those</p> <p>21 items provided to you by Plaintiffs' counsel?</p> <p>22 MS. PARFITT: Objection. Asked and</p> <p>23 answered.</p> <p>24 THE WITNESS: I don't -- I don't think</p> <p>25 so.</p>
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<p>1 Q. When you provided your opinion in March of</p> <p>2 2018 in the Ingham case, did you do so based on a</p> <p>3 comprehensive review of the literature?</p> <p>4 A. I think that -- yes, I believe that it was a</p> <p>5 comprehensive review, particularly of the</p> <p>6 epidemiologic data.</p> <p>7 Q. Why did you expand your list of references</p> <p>8 and materials considered for the MDL?</p> <p>9 A. I think just as you acquire, you know, become</p> <p>10 aware of more references, maybe if there were any new</p> <p>11 publications, or just as I expanded the knowledge,</p> <p>12 I think that it would be appropriate to include more</p> <p>13 references.</p> <p>14 Q. Do you know that a number -- a large number</p> <p>15 of the new references and materials considered were</p> <p>16 available in the public domain or in the -- in this</p> <p>17 litigation at the time that you gave your March 2018</p> <p>18 deposition?</p> <p>19 MS. PARFITT: Objection. Form.</p> <p>20 THE WITNESS: It would not surprise me</p> <p>21 to say that -- to see that some of them were there.</p> <p>22 BY MR. JAMES:</p> <p>23 Q. So, to be clear, the additional materials</p> <p>24 that you have added between March 2018 and your MDL</p> <p>25 report, those materials are not simply materials that</p>	<p>1 BY MR. JAMES:</p> <p>2 Q. Would you say the majority of the items that</p> <p>3 you've added from March 2018 to your MDL report were</p> <p>4 provided to you by Plaintiffs' counsel?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 THE WITNESS: I don't know what</p> <p>7 quantity, what fraction was provided by counsel and</p> <p>8 which I identified.</p> <p>9 MR. JAMES: Okay. I'm going to mark as</p> <p>10 Exhibit No. 10 a copy of your references and materials</p> <p>11 considered list for the MDL report.</p> <p>12 (Exhibit No. 10 was marked for identification.)</p> <p>13 BY MR. JAMES:</p> <p>14 Q. Okay. Dr. Moorman --</p> <p>15 MS. PARFITT: Just one correction,</p> <p>16 Mr. James. I think Exhibit 10 is just identified as</p> <p>17 "references." I believe you characterized it as</p> <p>18 "references and material considered."</p> <p>19 MR. JAMES: Yeah. I think if you keep</p> <p>20 flipping, Michelle -- or Ms. Parfitt -- it contains</p> <p>21 both.</p> <p>22 MS. PARFITT: Fair enough.</p> <p>23 BY MR. JAMES:</p> <p>24 Q. Okay. And you see, Dr. Moorman, if you've</p> <p>25 had a chance to flip through it while counsel have</p>

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<p>1 been talking, you see that this Exhibit 10 includes 2 some highlighting; right? 3 A. Yes. 4 Q. The highlighting, I'll state for the record, 5 represents our effort to capture the items that have 6 been added between Ingham and your MDL report. 7 Do you see that highlighting? 8 A. Mm-hmm. 9 Q. Again, I think we discussed this earlier, but 10 does it surprise you to find out that there are 94 new 11 items on the two MDL lists? 12 MS. PARFITT: Objection. Asked and 13 answered. 14 THE WITNESS: Again, I believe that 15 I answered that question previously. 16 BY MR. JAMES: 17 Q. 13 of the 20 references that are new were 18 available to you as of March 2018. Did you know that? 19 MS. PARFITT: Objection. Asked and 20 answered. 21 THE WITNESS: Again, I answered the 22 question when you asked it previously. 23 BY MR. JAMES: 24 Q. I don't think that we've talked specifically 25 about the references, but the references -- the</p>	<p>1 "search terms" or the primary search that was done, it 2 was very simple. It was "talc" or "talcum powder" and 3 "ovarian cancer." But many times, the initial search 4 will not generate all of the articles that you would 5 need to describe the science. There may be additional 6 articles, either things that I was aware of or 7 different searches that might be done. 8 But the overall search term to find the 9 literature on talc and ovarian cancer, I did not 10 change that. 11 Would it be a good time to take a break? 12 We've been going for over an hour. 13 MR. JAMES: For sure. 14 MS. PARFITT: Certainly. 15 THE VIDEOGRAPHER: Going off record at 16 10:05 a.m. 17 (Recess taken from 10:05 a.m. to 10:18 a.m.) 18 THE VIDEOGRAPHER: Back on record at 19 10:18 a.m. 20 BY MR. JAMES: 21 Q. Dr. Moorman, are you ready to proceed? 22 A. I am. 23 Q. Great. Dr. Moorman, do you consider yourself 24 to be an expert in animal studies and talc? 25 A. No, I do not.</p>
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<p>1 references that you've cited to your MDL report, those 2 are materials that you say form the opinions issued in 3 your MDL report; correct? 4 A. Yes. 5 Q. And you added 20 new references from your 6 Ingham list to your MDL report. Do you know that? 7 A. I know that there are new references, yes. 8 Q. And did you know that 13 of the 20 new 9 references -- again, the references are the list of 10 materials that formed your MDL report -- those were 11 available before March 2018? Did you know that? 12 A. I am aware that some of them were available. 13 Would like to make the point that many of 14 the points that I make in my report can be supported 15 by many, many references. And so the fact that 16 I added new references, that's really not too 17 surprising. It's -- again, if I felt like wanted to 18 emphasize a point more strongly, including additional 19 references, I don't think that would be surprising to 20 add additional references. 21 Q. Did you change your standards or search terms 22 that you used in the Ingham literature review for the 23 MDL review? 24 MS. PARFITT: Objection to form. 25 THE WITNESS: When we talk about</p>	<p>1 Q. Do you consider yourself to be an expert in 2 cell studies and talc? 3 A. No, I do not. 4 Q. Okay. Do you consider yourself to be an 5 expert in cytotoxicity studies and talc? 6 A. No, I do not. 7 Q. Do you consider yourself to be an expert in 8 mutagenicity studies and talc? 9 A. No, I do not. 10 Q. Do you consider yourself to be an expert in 11 genotoxicity studies and talc? 12 A. No, I do not. 13 Q. Do you consider yourself to be an expert in 14 mineral testing methods? 15 A. No, I do not. 16 Q. Okay. Do you consider yourself an expert in 17 mineral characterization? 18 A. No, I do not. 19 Q. Do you consider yourself to be an expert in 20 cancer biology? 21 A. I am not a cancer biologist; however, I 22 consider cancer biology frequently in my work. 23 Q. Do you consider yourself to be an expert in 24 geology? 25 A. No, I do not.</p>

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<p>1 Q. And do you consider yourself to be an expert 2 in mining? 3 A. No, I do not. 4 Q. Do you have expertise in pathology? 5 A. I -- once again, I am not a pathologist. 6 Sometimes rely on pathology and have collaborated with 7 pathologists, but I am not an expert pathologist. 8 Q. And would you agree do that not have 9 expertise in pathology? 10 MS. PARFITT: Objection. Asked and 11 answered. 12 THE WITNESS: You asked that I -- I do 13 not have expertise in pathology. I stated that I am 14 not a pathologist, but I do know some pathology from 15 my work in ovarian cancer and other cancers over the 16 years. So to say that I have no expertise isn't -- 17 I don't think that is correct. But we both -- I 18 acknowledge that I am not a trained pathologist. 19 BY MR. JAMES: 20 Q. Do you recall being asked in Ingham if you 21 considered yourself to have expertise in pathology? 22 A. I don't recall that question, specifically. 23 Q. I'm going to hand you a copy of the 24 transcript from Ingham that I brought with me, and I'm 25 going to refer you --</p>	<p>1 BY MR. JAMES: 2 Q. Have you done anything between your March 3 deposition and today in regards to obtaining expertise 4 in pathology? 5 A. No, I have not. 6 Q. Dr. Moorman, that's all I have on the 7 transcript for right now. 8 Dr. Moorman, do you agree that, prior to 9 offering expert opinion on a particular topic, an 10 expert should be conducted to -- expected to conduct a 11 comprehensive review of the medical and scientific 12 literature on that topic? 13 A. I'm sorry, I'm reading the question. 14 I -- I think that it is important to be 15 comprehensive. I think it's also important to 16 recognize that there are expertise in different areas. 17 And so we recognize that my expertise is in 18 epidemiology, and I have supplemented that with 19 other -- information from other areas as well. 20 Q. And with respect to the epidemiology on talc 21 and ovarian cancer, do you believe you conducted a 22 comprehensive review of that body of literature? 23 A. I believe that I have. 24 Q. Do you believe you conducted a comprehensive 25 review of the literature and scientific evidence on</p>
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<p>1 MR. JAMES: And, Ms. Parfitt, I have 2 two copies, unfortunately, not three. And this will 3 be just a couple questions, Ms. Parfitt. So if you 4 bear with me -- 5 MS. PARFITT: You can just direct me to 6 the page. 7 MR. JAMES: Sure. Looking at page 280. 8 MS. PARFITT: Just bear with us both -- 9 me. All right. 10 MR. JAMES: I'm looking at lines 12 11 through 14. 12 MS. PARFITT: Thank you. 13 BY MR. JAMES: 14 Q. Do you see the question, Dr. Moorman, where 15 you were asked if you have expertise in pathology? 16 Do you see that question? 17 A. I do. 18 Q. Okay. And you answered that you do not; 19 correct? 20 MS. PARFITT: Objection. 21 THE WITNESS: Yes, that is how 22 I answered. I think that the more qualified answer 23 that I gave today is probably a more accurate 24 representation. 25</p>	<p>1 mechanism? 2 A. I considered the scientific mechanisms and, 3 again, recognizing what my expertise is. As I have 4 indicated earlier, I am not a cancer biologist. I'm 5 not a laboratory scientist. I consider some of that 6 data, but I recognize that I am not -- you know, that 7 is not my major area of expertise. 8 Q. And I do understand from your MDL report that 9 you considered biology; correct? 10 A. I did consider biology. 11 Q. And so my precise question is whether you 12 conducted a comprehensive review on the issue of 13 mechanism. 14 MS. PARFITT: Objection. Asked and 15 answered. 16 THE WITNESS: I considered it, and, 17 again, I think that there is information out there 18 that a cancer biologist would have the expertise to 19 review it in more detail because of their training, 20 which is different than the training and expertise 21 that I have. 22 MR. JAMES: I object to the 23 nonresponsive portion of the answer. 24 BY MR. JAMES: 25 Q. Dr. Moorman, did you conduct a comprehensive</p>

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<p>1 review of all of the literature on animal studies and 2 talc? 3 MS. PARFITT: Objection. Form. 4 THE WITNESS: I don't believe that -- I 5 cannot say that I considered -- identified or 6 considered every animal study. 7 MR. JAMES: Object to the nonresponsive 8 answer. 9 BY MR. JAMES: 10 Q. Did you conduct a comprehensive review of the 11 literature on animal studies and talc? 12 MS. PARFITT: Asked and answered. 13 Objection. 14 THE WITNESS: I -- I believe that 15 I answered your question. I said that I don't think 16 that I identified or considered every animal study 17 related to talc and ovarian cancer. 18 BY MR. JAMES: 19 Q. Did you conduct a comprehensive review of 20 cell studies and talc? 21 A. Once again, I considered some of that 22 literature. Whether it was comprehensive or not, I -- 23 I don't think that I have the expertise to say that 24 I considered all of the cell studies and talc. 25 Q. Did you conduct a comprehensive review on the</p>	<p>1 have referred to another article. 2 Q. Did you conduct a comprehensive review of the 3 genotoxicity studies that are relevant to talc and 4 ovarian cancer? 5 A. My answer to this question is similar to the 6 answers that I have given there. 7 I have read some of the mechanistic studies. 8 I would not say that I necessarily identified every 9 relevant genotoxicity study. 10 Q. And I'm not asking you, Dr. Moorman, if you 11 did find 100 percent of the studies. I'm asking you 12 if part of your review in this case began with the 13 intention to capture that body of literature. 14 MS. PARFITT: Objection. Asked and 15 answered several times. 16 THE WITNESS: My intent was, as an 17 epidemiologist, was to be very comprehensive in my 18 area of expertise. There were certainly some other 19 related areas where I reviewed the literature, but 20 there are experts that will speak to that more 21 directly because of their expertise. 22 BY MR. JAMES: 23 Q. Okay. So will you agree with me today that 24 you have not conducted a comprehensive review of the 25 cell studies and talc?</p>
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<p>1 issue of migration in this case? 2 A. I believe -- again, I considered every study 3 that I was aware of on migration of talc. It's a 4 little bit outside my area of expertise, so I am not 5 sure that I identified every single study in that 6 regard. 7 Q. And with the methods that you applied in this 8 case, was it your intention to capture every study 9 pertaining to the issue of migration? 10 MS. PARFITT: Objection. Form. 11 THE WITNESS: I tried -- you know, my 12 intent was to read the articles that I was aware of, 13 that were brought to my attention. Because it is a 14 little bit outside my area of expertise, I cannot say 15 with 100 percent certainty that I identified every 16 single study related to migration. 17 BY MR. JAMES: 18 Q. But you testified that your intent was to 19 read the articles that you are aware of or that were 20 brought to your attention. 21 When you say brought to your attention, was 22 that by Plaintiffs' counsel? 23 A. It's some -- some of them could have been 24 brought to my attention in that way. Some of them 25 could have been -- like, an article that I read might</p>	<p>1 MS. PARFITT: Objection. Misstates her 2 testimony. 3 You may answer, Dr. Moorman. 4 THE WITNESS: I -- I think that -- 5 I think that it is fair to say that I have probably 6 not reviewed every cell study and talc. 7 BY MR. JAMES: 8 Q. Okay. Dr. Moorman, I'm going to refer you 9 back to the Ingham transcript, please, that's in front 10 of you. 11 MS. PARFITT: Are we marking this, 12 Scott? 13 MR. JAMES: We can. Sure. 14 Dr. Moorman, when we finish this, I'll take 15 that back from you and mark it as Exhibit No. 11. 16 Okay? 17 (Exhibit No. 11 was marked for identification.) 18 BY MR. JAMES: 19 Q. Dr. Moorman, if you look at page 35 of your 20 transcript, please. And if you look at lines -- it's 21 lines 11 through 17. It's a question and answer. If 22 you could review that for me. 23 A. Okay. 24 Q. And do you see that on line 16, you answered 25 in Ingham:</p>

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<p>1 "I have not done a comprehensive 2 review of those studies." 3 And there, you're referring to cell studies; 4 correct? 5 A. Yes, that is what it says here. 6 Q. Is that a truthful answer? 7 A. I think -- 8 MS. PARFITT: Objection. Form. 9 Go ahead. 10 THE WITNESS: I think that we -- you 11 know, as you have asked me the questions and I have 12 responded to them, that it's -- I have looked at some 13 of these studies. I would not have looked at all of 14 them. 15 BY MR. JAMES: 16 Q. As an epidemiologist, do you understand the 17 significance of the term "comprehensive review"? 18 A. Yes, I understand the term. 19 Q. Okay. And you understand that you have 20 testified that you conducted a comprehensive review of 21 the epidemiology literature for talc and ovarian 22 cancer; correct? 23 MS. PARFITT: Asked and answered. 24 THE WITNESS: Yes. 25</p>	<p>1 literature in greater detail. 2 Q. Have you undertaken a comprehensive review of 3 literature pertaining to the allegation that asbestos 4 may contaminate talcum powder products? 5 MS. PARFITT: Objection. Form. 6 THE WITNESS: A comprehensive review of 7 the literature pertaining to the allegation that 8 asbestos may contaminate talcum powder? 9 I have read quite a few articles and 10 documents addressing that. Whether or not I have read 11 every document addressing that, I'm not absolutely 12 sure. 13 BY MR. JAMES: 14 Q. Okay. Dr. Moorman, you're answering a 15 question that I didn't ask. And so I object to the 16 nonresponsiveness again. 17 Did you conduct a comprehensive review of 18 the body of literature assessing whether asbestos 19 contaminates talcum powder products? 20 A. I believe that I have answered your question. 21 It's -- 22 Q. Could you please answer it again. 23 A. I have read many articles on it. I do not 24 know that I have read every article related to that 25 topic, again. So...</p>
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<p>1 BY MR. JAMES: 2 Q. And so I'm asking if you have applied the 3 same comprehensive review to these other areas, 4 including cell studies, animal studies, and mechanism 5 studies. 6 MS. PARFITT: Objection. Form. Asked 7 and answered. 8 BY MR. JAMES: 9 Q. Have you conducted the same comprehensive 10 review on that body of literature that you've 11 conducted on the epidemiology? 12 MS. PARFITT: Objection. 13 THE WITNESS: Once again, I have 14 answered the question. This is not my primary area of 15 expertise. And so I have not done the review to the 16 depth and the -- as comprehensive as I have done in my 17 area of expertise, which is epidemiology. 18 BY MR. JAMES: 19 Q. Have you done a comprehensive review of the 20 epidemiology on the relationship between asbestos and 21 ovarian cancer? 22 A. I believe that I have looked at a pretty 23 comprehensive -- I've had a pretty comprehensive look 24 at the asbestos and ovarian cancer. I believe that 25 I have looked at the talcum -- talc and ovarian cancer</p>	<p>1 Q. You understand that if you were going to 2 publish an opinion in peer-reviewed literature about 3 the allegation that asbestos contaminates talcum 4 powder products, you would be expected to conduct a 5 comprehensive review of that literature; correct? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: If I were to publish an 8 opinion in a peer-reviewed literature, you would want 9 to have a comprehensive review of the literature, yes. 10 BY MR. JAMES: 11 Q. And have you conducted a comprehensive review 12 of the literature on that topic, such that you would 13 feel comfortable providing an opinion for a 14 peer-reviewed journal? 15 MS. PARFITT: Objection. Form. 16 BY MR. JAMES: 17 Q. And the topic being the allegation that 18 asbestos contaminates talcum powder products. 19 MS. PARFITT: Objection. Form. 20 THE WITNESS: I think that I'm maybe 21 having some difficulty answering this question because 22 it would seem like this would be a topic that would be 23 more appropriately addressed by a mineralogist. And 24 I -- I actually cannot see myself writing a 25 peer-reviewed article about this because it seems</p>

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<p style="text-align: right;">Page 66</p> <p>1 somewhat -- it's related to the epidemiology of talc 2 and ovarian cancer, but I would not be writing an 3 article focused solely on that. 4 BY MR. JAMES: 5 Q. You understand that, in your expert report, 6 you have opined with -- that there's "credible 7 evidence" there has been asbestos in talcum power 8 products. 9 Do you recall making that conclusion in your 10 report? 11 A. Yes. 12 Q. So to support that conclusion that you 13 believe there's "credible evidence" in talcum powder 14 products, did you conduct a systematic review of the 15 literature to support that conclusion? 16 A. I did not -- 17 MS. PARFITT: I'm going to object to 18 the form of the question. Some words were left out. 19 You may answer. 20 THE WITNESS: In my report, I cited 21 literature that did support that opinion. 22 Did I conduct a systematic review that 23 identified possibly every piece of literature that 24 addressed the topic? No, I did not do that. 25</p>	<p style="text-align: right;">Page 68</p> <p>1 A. It was part of the basis for my opinion, 2 along with some peer-reviewed literature. 3 Q. Okay. With respect to the company documents, 4 were those documents hand-selected for you by 5 Plaintiffs' counsel? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: They were provided to me 8 by Plaintiffs' counsel. 9 BY MR. JAMES: 10 Q. Okay. When you saw those documents, did you 11 ask if there were additional documents that would 12 address the issue of asbestos contamination? 13 A. I don't know that I asked if there were 14 additional documents. It was my impression that there 15 were probably many other documents related to this 16 that were not provided to me. 17 Q. And as a scientist, wouldn't you be 18 interested in knowing if there are other documents 19 that have been produced in this litigation that rebut 20 the claim that asbestos contaminates talcum powder 21 products? 22 MS. PARFITT: Objection. Form. 23 THE WITNESS: This is an interesting 24 question because the claim had been made that 25 asbestos -- or, rather, that talcum -- talcum powder</p>
<p style="text-align: right;">Page 67</p> <p>1 BY MR. JAMES: 2 Q. Do you believe that the standards for 3 providing opinions in litigation reports differ from 4 the standards for providing opinions in published 5 literature? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: No. No. I think that 8 one is trying to provide evidence to support one's 9 opinions. 10 BY MR. JAMES: 11 Q. With respect to the issue of asbestos 12 contamination, Dr. Moorman, you said you did review 13 some articles. 14 How did you characterize that? 15 A. I said that I reviewed some -- some articles 16 and some -- some documents. I don't think that 17 I reviewed every article or document that is available 18 on that topic. 19 Q. With respect to documents, are you referring 20 to company documents provided to you by Plaintiffs' 21 counsel? 22 A. That -- that's part of what I reviewed, some 23 of those documents provided by counsel. 24 Q. And looking at those documents provided the 25 basis for your opinion; is that right?</p>	<p style="text-align: right;">Page 69</p> <p>1 products had been asbestos-free since 1976. And it 2 is -- the documents provided, including the 3 peer-reviewed as well as the other, saying that -- 4 provide evidence that that is not an accurate 5 statement. 6 We're not saying that every container of 7 talcum powder contains asbestos, but what I was saying 8 in my report is that there is evidence that some 9 talcum powder products have asbestos in them. 10 MR. DONATH: Move to strike, 11 nonresponsive. 12 BY MR. JAMES: 13 Q. So are you changing your report -- because in 14 the report, you say that there is "credible evidence." 15 Do you recall making that conclusion? 16 A. Yes. 17 Q. As a scientist, you understand that to give 18 something credit, you would necessarily need to 19 consider both sides of the story; correct? 20 MS. PARFITT: Objection. Misstates her 21 testimony. She's... 22 You can answer, Dr. Moorman. 23 THE WITNESS: I'm sorry? 24 MS. PARFITT: I said it misstates what 25 you're trying to suggest to the ladies and gentlemen</p>

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<p>1 of the jury.</p> <p>2 But if you can answer that question again,</p> <p>3 please try and answer Mr. James' question. And</p> <p>4 look -- if you need to look at the question, please</p> <p>5 do.</p> <p>6 THE WITNESS: I think that I did -- it</p> <p>7 says "As a scientist, you understand that to give</p> <p>8 something credit, you would necessarily need to</p> <p>9 consider both sides of the story."</p> <p>10 And I think that I did consider both sides</p> <p>11 of the story.</p> <p>12 I think that, as I stated, the evidence does</p> <p>13 not suggest that every container of talcum powder has</p> <p>14 detectable asbestos in it. But my statement that</p> <p>15 there is credible evidence that some talcum powder</p> <p>16 products contain asbestos, I think that that statement</p> <p>17 is absolutely true. There is some evidence to</p> <p>18 indicate that some talcum powder -- or asbestos has</p> <p>19 been identified in some talcum powder products.</p> <p>20 BY MR. JAMES:</p> <p>21 Q. Do you understand what Johnson & Johnson's</p> <p>22 position is with respect to that claim?</p> <p>23 A. I -- I don't know specifically. Perhaps you</p> <p>24 could -- could tell me.</p> <p>25 Q. You understand that Johnson & Johnson's</p>	<p>1 company documents and other materials to support your</p> <p>2 conclusions about asbestos contamination?</p> <p>3 A. I -- I wouldn't be able to quantify that.</p> <p>4 I don't know specifically.</p> <p>5 Q. Can you give us an estimate?</p> <p>6 A. I think it would be pretty difficult to come</p> <p>7 up with an estimate. You know, I read some documents</p> <p>8 from the company. I read documents -- some</p> <p>9 peer-reviewed literature. I reviewed documents</p> <p>10 provided by Plaintiffs' counsel.</p> <p>11 Perhaps -- I don't know. Perhaps ten -- ten</p> <p>12 hours or so.</p> <p>13 Q. When you said that you reviewed company</p> <p>14 documents, again, those are the documents provided to</p> <p>15 you by Plaintiffs' counsel; correct?</p> <p>16 A. Yes.</p> <p>17 MS. PARFITT: Objection. Form.</p> <p>18 THE WITNESS: Yes, the Plaintiff</p> <p>19 provided those documents to me.</p> <p>20 BY MR. JAMES:</p> <p>21 Q. And you did not ask Plaintiffs' counsel to</p> <p>22 provide you additional documents once you saw the</p> <p>23 first batch of documents; correct?</p> <p>24 MS. PARFITT: Objection. Form.</p> <p>25 THE WITNESS: I did not ask, no.</p>
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<p>1 position is that talcum powder products have not been</p> <p>2 contaminated with asbestos? Do you know that that's</p> <p>3 Johnson & Johnson's position?</p> <p>4 A. I -- if you are telling me that now, I don't</p> <p>5 know that I have -- I -- I'm trying to think what</p> <p>6 I have read. I think that, yes, I have probably read</p> <p>7 statements from the company that describes that as</p> <p>8 their position.</p> <p>9 Q. And do you know what Johnson & Johnson bases</p> <p>10 their position on?</p> <p>11 A. Not specifically.</p> <p>12 Q. Wouldn't that be pretty important to</p> <p>13 understand before making an opinion about whether</p> <p>14 there's credible evidence of asbestos contamination?</p> <p>15 MS. PARFITT: Objection. Form.</p> <p>16 THE WITNESS: Again, I think that when</p> <p>17 one is trying to make a statement that there is no</p> <p>18 asbestos contained in talc products, if you are</p> <p>19 finding evidence from multiple sources that there is</p> <p>20 asbestos contained in some talc products, that</p> <p>21 supports the statement that I made in report that</p> <p>22 there is credible evidence that not all talc products</p> <p>23 are asbestos-free.</p> <p>24 BY MR. JAMES:</p> <p>25 Q. How many hours did you spend reviewing</p>	<p>1 BY MR. JAMES:</p> <p>2 Q. You also looked at litigation reports from</p> <p>3 Plaintiffs' expert regarding asbestos contamination;</p> <p>4 correct?</p> <p>5 A. Yes, I did.</p> <p>6 Q. And you understand those experts are paid</p> <p>7 litigation experts by the Plaintiffs; correct?</p> <p>8 MS. PARFITT: Objection. Form.</p> <p>9 THE WITNESS: Yes, I understand that</p> <p>10 they are paid by the Plaintiffs.</p> <p>11 BY MR. JAMES:</p> <p>12 Q. One of those experts is Longo; correct?</p> <p>13 A. That is correct.</p> <p>14 MS. PARFITT: Is that Dr. Longo?</p> <p>15 MR. JAMES: Thank you, Michelle.</p> <p>16 BY MR. JAMES:</p> <p>17 Q. Dr. Longo; is that correct?</p> <p>18 A. That is correct.</p> <p>19 Q. Okay. So you reviewed Dr. Longo's reports?</p> <p>20 A. I looked at them, yes.</p> <p>21 Q. Okay. Do you understand that in this</p> <p>22 litigation, Johnson & Johnson has presented experts to</p> <p>23 rebut Dr. Longo's findings?</p> <p>24 MS. PARFITT: Objection. Just let the</p> <p>25 record reflect that the defense expert reports have</p>

19 (Pages 70 to 73)

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<p>1 not yet been provided in this litigation, in the MDL 2 litigation, so it would have been difficult to provide 3 that to Dr. Moorman. 4 BY MR. JAMES: 5 Q. You can still answer the question. 6 A. It would not surprise me to know that there 7 were reports provided by -- that was done for the 8 defense, but I have not seen them. 9 Q. Did you ask to see them? 10 MS. PARFITT: Objection. Form. 11 THE WITNESS: I did not ask to see -- 12 no, I did not. 13 BY MR. JAMES: 14 Q. And counsel just made a note on the record 15 about these litigation reports from the defense not 16 being made available yet in the MDL. 17 Do you understand that the defense has 18 presented experts, for example, in the Ingham case to 19 rebut Dr. Longo's findings? 20 A. I was not specifically aware of that. It 21 would not surprise me, however. 22 Q. You understand Dr. Longo's litigation reports 23 that you reviewed, those are not peer-reviewed. 24 Do you understand that? 25 MS. PARFITT: Objection. Form.</p>	<p>1 there's no safe level of asbestos, that any level of 2 asbestos in a talcum powder product is bad for the 3 health of the people who use it. 4 Q. Do you intend to offer any opinions about the 5 purported amount of contamination in talcum powder 6 products over the course of history? 7 MS. PARFITT: Objection. Form. 8 THE WITNESS: I am not going to offer 9 an opinion about the quantity of asbestos in talcum 10 powder products. 11 BY MR. JAMES: 12 Q. Have you, in the course of forming your 13 opinions in this case, ever reviewed the FDA testing 14 of talcum powder products for the presence of 15 asbestos? 16 A. I recall reviewing a document from FDA, yes. 17 Q. Okay. And that document is not discussed in 18 your report, is it? 19 A. No, I don't think that I specifically 20 reference that. 21 Q. Why is that? 22 A. I don't -- I don't know why I didn't 23 reference it. I read it, but... 24 MR. JAMES: I'm marking Exhibit No. 11 25 [sic], talc testing information from the FDA, that I'm</p>
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<p>1 THE WITNESS: Yes, I know that they are 2 not peer-reviewed. 3 BY MR. JAMES: 4 Q. With regard to the literature that you've 5 referenced having reviewed pertaining to the 6 allegation that talcum powder products are 7 contaminated with asbestos, what does that literature 8 say about Johnson & Johnson products specifically? 9 A. I'm trying to recall specifically. I believe 10 that some of the articles were not specific about the 11 particular brand names that they tested. I think they 12 just described them as commercially available 13 products. But I believe that -- I want to say that 14 I recall at least one that described the products as 15 being Johnson & Johnson. 16 Q. With respect to everything that you reviewed 17 pertaining to your claim in your report of "credible 18 evidence" of contamination of talcum powder products, 19 what did everything you reviewed tell us about the 20 amount of contamination in the products? 21 Do you have any opinions about amount? 22 A. I do. My opinions are that most of the 23 analyses that detected asbestos fibers in talcum 24 powder products detected low levels, and putting that 25 in the context that asbestos has been characterized as</p>	<p>1 handing you, Dr. Moorman. 2 (Exhibit No. 12 was marked for identification.) 3 MR. JAMES: I provided an extra copy if 4 you want to hand one to your counsel, please. Thank 5 you much. 6 MR. FARIES: This is 12. 7 MS. PARFITT: 11 is the transcript. 8 MR. JAMES: Got it. Thank you. I'll 9 fix the sticker once we finish the question. 10 MS. PARFITT: No worries. 11 BY MR. JAMES: 12 Q. Okay. Dr. Moorman, is this the document that 13 you had seen before? 14 A. I'm not sure if this is the same one or if 15 I -- no, I -- actually, I think that I did see this. 16 Q. And if you look over on page 2 of the 17 exhibit -- it's page 2 of 8 -- do you see at the 18 bottom, it says in the section "The results of FDA's 19 survey" -- do you see where I'm reading? 20 A. Yes. 21 Q. And the FDA here says (as read): 22 "The survey found no asbestos 23 fibers or structures in any of the 24 samples of cosmetic-grade raw 25 material talc or cosmetic products</p>

20 (Pages 74 to 77)

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<p>1 containing talc." 2 Did I read that correctly? 3 A. You did. 4 MS. PARFITT: Are you going to complete 5 this paragraph, or are you going to leave it at that? 6 MR. JAMES: Michelle, you'll have an 7 opportunity to ask your questions. 8 MS. PARFITT: Well, just for 9 completeness. Certainly, if that's how you'd like to 10 handle it, that's fine. 11 MR. JAMES: Okay. That's how it works. 12 MS. PARFITT: Oh, I -- Scott, you don't 13 have to educate me on how it works. I get how you're 14 working, and we'll make it work on our side too. 15 Thank you. 16 BY MR. JAMES: 17 Q. Dr. Moorman, is that conclusion cited 18 anywhere in your report? 19 A. That -- 20 MS. PARFITT: Objection to the partial 21 conclusion. 22 Please answer. 23 THE WITNESS: Right. It's -- I did not 24 put it in there. However, I considered as I was, you 25 know, evaluating this literature, what it goes on to</p>	<p>1 proportion of the talcum powder products in the US are 2 Johnson & Johnson products. 3 Q. Do you know if the FDA test results 4 specifically pertain to Johnson & Johnson products? 5 A. I'm -- I believe that some of the products 6 tested -- I believe that some of them were Johnson & 7 Johnson products, if I'm not mistaken. But I can't 8 say that with certainty. 9 Actually, when I look at the report, I do 10 see that they list Johnson's baby powder. 11 Q. And, Dr. Moorman, you're referring to page 7; 12 correct? 13 A. Yes. 14 Q. Okay. Do you understand that the FDA also 15 tested samples provided to them by the supplier of 16 talc for Johnson & Johnson products? Did you know 17 that? 18 A. I -- I think that I knew that. I believe 19 I did know that. 20 Q. Again, that's not quoted anywhere in your 21 report either, is it? 22 A. No, that is -- 23 MS. PARFITT: Object to form. 24 THE WITNESS: -- not. 25</p>
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<p>1 say (as read): 2 "The results were limited by the 3 fact that only four talc suppliers 4 submitted samples and by the 5 number of products tested." 6 BY MR. JAMES: 7 Q. Okay. 8 A. And so it goes on to say, you know, 9 (as read): 10 "They do not prove that most or 11 all talc or talc-containing 12 cosmetic products currently 13 marketed in the US are likely to 14 be free of asbestos 15 contamination." 16 So... 17 Q. You're offering opinions in the MDL -- let me 18 re-ask this. 19 Are you offering opinions in the MDL that 20 Johnson & Johnson talcum powder products have been 21 contaminated with asbestos at some point in time? 22 A. In my opinion, I am referring to talcum 23 powder products. Okay? I don't believe in my report, 24 I ever specifically say Johnson & Johnson talcum 25 powder products, but I do recognize that a large</p>	<p>1 BY MR. JAMES: 2 Q. Before offering opinions about "credible 3 evidence," don't you think it would be important to 4 mention the findings of the FDA on such an important 5 issue? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: As I have stated before, 8 my opinion was that there is credible evidence that -- 9 from peer-reviewed articles, from some other sources 10 as well, that asbestos has been found in talcum powder 11 products. I believe that that evidence is credible. 12 I did not make the statement that it is in 13 all products, but I think that my statement that there 14 is credible evidence that some talcum powder products 15 contain asbestos I think is accurate. 16 BY MR. JAMES: 17 Q. And is that a conclusion that you would feel 18 comfortable providing in published peer-reviewed 19 literature? 20 MS. PARFITT: Objection. Form. 21 THE WITNESS: To say that there is 22 credible evidence that some talcum powder products 23 contain asbestos, I think that that -- I would feel 24 comfortable saying that based on peer-reviewed 25 literature that has found that.</p>

21 (Pages 78 to 81)

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<p>1 BY MR. JAMES: 2 Q. But you never undertook an effort to conduct 3 a comprehensive review of the literature on the topic, 4 did you? 5 MS. PARFITT: Objection. Form. Asked 6 and answered several times. 7 THE WITNESS: Yes, I feel like I -- you 8 have asked that, and I think that I have answered it. 9 BY MR. JAMES: 10 Q. What's your answer? 11 A. My answer is that I have found evidence 12 that -- from peer-reviewed literature, from other 13 documents, that some asbestos has been detected in 14 some talcum powder products. 15 Q. With regard to the company documents that you 16 reviewed that were provided to you by Plaintiffs' 17 counsel, do you consider yourself an expert in 18 reviewing the information conveyed by those documents? 19 MS. PARFITT: Objection. Form. 20 THE WITNESS: As I have indicated 21 previously, I am not a mineralogist or a geologist, 22 and so I would not consider myself an expert in 23 reviewing those types of documents. 24 BY MR. JAMES: 25 Q. Do you have any knowledge about the</p>	<p>1 BY MR. JAMES: 2 Q. Dr. Moorman, have you seen a 2014 letter from 3 the FDA addressing a request for a warning on talcum 4 powder products? 5 A. Yes, I have. 6 Q. Do you know that within that letter, the FDA 7 comments on the issue of alleged asbestos 8 contamination? 9 MS. PARFITT: Objection. Form. 10 THE WITNESS: If I could see the 11 document. It has been a while since I have actually 12 looked at it. 13 BY MR. JAMES: 14 Q. Absolutely. 15 MR. JAMES: And if counsel could remind 16 me, are we now on 13? 17 MS. PARFITT: We are indeed. 18 MR. JAMES: Thank you. 19 MS. PARFITT: You are very welcome. 20 (Exhibit No. 13 was marked for identification.) 21 BY MR. JAMES: 22 Q. Okay. Dr. Moorman, I'm handing you a copy of 23 the 2014 FDA letter with an extra copy to pass to your 24 counsel. 25 MS. PARFITT: Thank you.</p>
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<p>1 specifications that are used by Johnson & Johnson in 2 manufacturing its talcum powder products? 3 A. No, I do not. 4 Q. Do you have any expertise in the sufficiency 5 of the specifications to detect the presence of 6 asbestos? 7 A. No, I do not. 8 Q. Did you know that Johnson & Johnson produces 9 its talcum powder products in accordance with 10 specifications set out by the US Pharmacopeial 11 Convention? 12 MS. PARFITT: Objection. Form. 13 THE WITNESS: I was not specifically 14 aware of that. I don't know what their specifications 15 are. 16 BY MR. JAMES: 17 Q. Did Plaintiffs' counsel provide to you those 18 specifications? 19 A. Not that I recall. 20 Q. Did you know that the specifications provide 21 mechanisms to test for the absence of asbestos? 22 MS. PARFITT: Objection. Form. 23 THE WITNESS: I have already stated 24 that I -- I don't know what those specifications are. 25</p>	<p>1 BY MR. JAMES: 2 Q. Dr. Moorman, if you could turn to the second 3 page of the letter. Is this the letter that you've 4 seen before, Dr. Moorman? 5 A. Yes, it is. 6 Q. And do you see that, in the section entitled 7 "Chemistry Findings," there's a discussion there by 8 the FDA pertaining to asbestos; correct? 9 A. Yes, I see that. 10 Q. And do you see that at the bottom of the 11 letter, the very last sentence, the FDA says 12 (as read): 13 "You have not provided evidence 14 that asbestos-contaminated 15 talc-containing cosmetic products 16 are currently being marketed, 17 since the data submitted is almost 18 40 years old." 19 Do you see that? 20 A. I do see that. 21 Q. Okay. And you said that you have reviewed 22 this letter in its entirety before? 23 A. I have read it, yes. 24 Q. Do you have any reason to quarrel with the 25 scientists at the FDA that have looked at the issue of</p>

22 (Pages 82 to 85)

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<p>1 asbestos contamination in talcum powder products?</p> <p>2 MS. PARFITT: Objection. Form.</p> <p>3 THE WITNESS: I don't know who those</p> <p>4 scientists are. I don't know any scientists at the</p> <p>5 FDA who would have done -- would have done this. I --</p> <p>6 so I can't say that I have a quarrel with them because</p> <p>7 I don't know them.</p> <p>8 BY MR. JAMES:</p> <p>9 Q. Do you have any opinions about the type of</p> <p>10 asbestos that is alleged to contaminate talcum powder</p> <p>11 products?</p> <p>12 A. I am certainly aware that there are different</p> <p>13 types of asbestos. Again, from a health perspective,</p> <p>14 there is no safe form of asbestos. So if there are</p> <p>15 different types, it really doesn't make a lot of</p> <p>16 difference in terms of the potential health effects.</p> <p>17 MR. JAMES: Object to the nonresponsive</p> <p>18 portion.</p> <p>19 BY MR. JAMES:</p> <p>20 Q. Do you intend to offer any opinions about the</p> <p>21 type of asbestos that Plaintiffs contend contaminates</p> <p>22 talcum powder products?</p> <p>23 A. No, I am not going to specifically address</p> <p>24 the types of asbestos in talcum powder products.</p> <p>25 Q. Do you hold the opinion that asbestos causes</p>	<p>1 Did you form your opinions about asbestos</p> <p>2 and talcum powder that are contained within your MDL</p> <p>3 report after being retained as an expert?</p> <p>4 MS. PARFITT: Object to form.</p> <p>5 THE WITNESS: I -- it is often -- has</p> <p>6 often been reported in the literature that talcum</p> <p>7 powder contained asbestos prior to 1976, and that</p> <p>8 products produced after that did not contain asbestos.</p> <p>9 And as I became involved in this litigation,</p> <p>10 I was made aware of and discovered some of the</p> <p>11 articles that showed that talcum powder products after</p> <p>12 1976 contained asbestos.</p> <p>13 And so my opinion was that -- my opinion</p> <p>14 that asbestos in current or recently marketed talcum</p> <p>15 powder products could explain -- was part of the</p> <p>16 biological mechanism by which exposure to talcum</p> <p>17 powder, that was -- that was formed as I became aware</p> <p>18 of more of the available information, when I became</p> <p>19 involved in this litigation.</p> <p>20 BY MR. JAMES:</p> <p>21 Q. Setting aside the issue of asbestos in talcum</p> <p>22 powder, do you believe that asbestos is a cause of</p> <p>23 ovarian cancer?</p> <p>24 A. Yes, I do.</p> <p>25 Q. How many studies have explored the link</p>
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<p>1 ovarian cancer?</p> <p>2 A. Yes.</p> <p>3 Q. Do you hold the opinion that exposure to</p> <p>4 asbestos through use of talcum powder products causes</p> <p>5 ovarian cancer?</p> <p>6 A. My opinion is based on exposure to talcum</p> <p>7 powder products and whatever is contained within them.</p> <p>8 And so if there is asbestos within talcum powder</p> <p>9 products, which we have some evidence to suggest that</p> <p>10 that is the case, then that provides a potential</p> <p>11 biological mechanism by which talcum powder products</p> <p>12 could cause ovarian cancer.</p> <p>13 Q. The opinion that you have pertaining to</p> <p>14 asbestos and ovarian cancer, did you form that opinion</p> <p>15 in the context of litigation?</p> <p>16 MS. PARFITT: Objection. Form.</p> <p>17 THE WITNESS: I'm not sure how -- could</p> <p>18 you perhaps restate the question?</p> <p>19 BY MR. JAMES:</p> <p>20 Q. Absolutely.</p> <p>21 A. I'm not sure --</p> <p>22 Q. Absolutely.</p> <p>23 A. -- what you're asking.</p> <p>24 Q. Did you form the opinion that -- did you</p> <p>25 form -- let me start over.</p>	<p>1 between asbestos and ovarian cancer?</p> <p>2 MS. PARFITT: Objection. Form.</p> <p>3 THE WITNESS: In terms of epidemiologic</p> <p>4 literature, there have been a couple of meta-analyses;</p> <p>5 and the exact number, I don't have that off the top of</p> <p>6 my head, but I want to say approximately a dozen</p> <p>7 studies.</p> <p>8 BY MR. JAMES:</p> <p>9 Q. Did you review the entire body of literature</p> <p>10 looking at a purported link between asbestos and</p> <p>11 ovarian cancer?</p> <p>12 MS. PARFITT: Objection. Form.</p> <p>13 THE WITNESS: I know that I looked at</p> <p>14 the meta-analyses. I looked at some data from IARC,</p> <p>15 and I believe that I have looked in some degree at,</p> <p>16 I think, all of the epidemiologic studies about</p> <p>17 asbestos and ovarian cancer.</p> <p>18 BY MR. JAMES:</p> <p>19 Q. So did you look at all of the studies that</p> <p>20 are discussed in the IARC monograph?</p> <p>21 MS. PARFITT: Objection. Form.</p> <p>22 THE WITNESS: I have -- the IARC</p> <p>23 monograph, as they typically do, they look at many of</p> <p>24 the animal studies, some of the laboratory studies.</p> <p>25 I have not looked at all of them. I have looked at</p>

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<p style="text-align: right;">Page 90</p> <p>1 the epidemiologic studies, which, again, is my area of 2 expertise. 3 BY MR. JAMES: 4 Q. And we're speaking currently about the IARC 5 monograph on asbestos; correct? 6 A. Correct. 7 Q. On page 34 of your report, if that you have 8 handy, Dr. Moorman -- actually, I think I have the 9 wrong page number. Give me one second. 10 Okay. It's actually page 35. My apologies. 11 And you see -- I'm looking at the first -- 12 the top paragraph. And you state in the second 13 sentence -- do you see where I am? It starts with 14 "IARC"? 15 A. Yes. 16 Q. Says (as read): 17 "IARC has stated that a causal 18 association between exposure to 19 asbestos and cancer of the ovary 20 was clearly established based on 21 strongly positive cohort mortality 22 studies of women with occupational 23 exposure to asbestos, as well as 24 studies of women with 25 environmental exposure to</p>	<p style="text-align: right;">Page 92</p> <p>1 Dr. Moorman. 2 A. Yes. 3 Q. Actually, 256 is where it carries into. And 4 on page 256, there's a section entitled "syntheses." 5 Do you see where I am, Dr. Moorman? 6 A. Yes. 7 Q. Okay. And if you look at the right-hand 8 column, it's the first full paragraph in the middle of 9 the page. 10 A. Yes. 11 Q. And there, the IARC states that (as read): 12 "The working group noted that a 13 causal association between 14 exposure to asbestos and cancer of 15 the ovary was clearly established 16 based on five strongly positive 17 cohort mortality studies of women 18 with heavy occupational exposure 19 to asbestos." 20 Do you see that? 21 A. Yes. 22 Q. Okay. And so the IARC then goes on to say, 23 in the next sentence, that the conclusion (as read): 24 "Received additional support from 25 studies showing that women and</p>
<p style="text-align: right;">Page 91</p> <p>1 asbestos." 2 A. Yes. 3 Q. Do you see where I was reading? 4 A. Yes. 5 Q. To be clear, Dr. Moorman, that's not 6 precisely how IARC has stated that, is it? 7 MS. PARFITT: Objection. Form. 8 THE WITNESS: I -- 9 BY MR. JAMES: 10 Q. I'm sorry, Doctor. 11 If I may, Dr. Moorman, I'll just provide you 12 a copy. Is that okay? 13 A. Okay. 14 Q. I'm going to mark as Exhibit 14 a copy of 15 the -- what we're referring to as the asbestos 16 monograph that's 100C. 17 (Exhibit No. 14 was marked for identification.) 18 MS. PARFITT: Mr. James, just for the 19 record, that's not the entire 100C monograph, is it? 20 MR. JAMES: Thank you. Thank you. Let 21 me clarify. This is excerpts of -- Exhibit 14 is 22 excerpts of the monograph. 23 MS. PARFITT: Thank you. 24 BY MR. JAMES: 25 Q. Okay. And if we turn to page 254,</p>	<p style="text-align: right;">Page 93</p> <p>1 girls with environmental, but not 2 occupational exposure to asbestos, 3 had positive, but nonsignificant, 4 increases in both ovarian cancer 5 incidence and mortality." 6 Do you see that? 7 A. Yes. 8 Q. And so the IARC's conclusion here with 9 respect to asbestos and ovarian cancer. 10 Again, this conclusion is being made outside 11 the context of talcum powders; correct? 12 A. Right. This is based on asbestos exposure. 13 Q. And the way that IARC has structured this 14 paragraph is that they have said that they've based 15 their conclusion on the occupational studies; correct? 16 MS. PARFITT: Objection. Form. 17 THE WITNESS: Yes. 18 BY MR. JAMES: 19 Q. And then they do note the additional support 20 after that sentence; correct? 21 MS. PARFITT: Objection to form. 22 THE WITNESS: Yes. 23 BY MR. JAMES: 24 Q. Okay. And just to be clear, the IARC here 25 acknowledges that the non-occupational studies report</p>

24 (Pages 90 to 93)

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<p>1 nonstatistically significant associations; correct?</p> <p>2 A. They note "positive, though nonsignificant</p> <p>3 increases."</p> <p>4 Yes, that's what it states.</p> <p>5 Q. And if you turn with me to page 280 of the</p> <p>6 same monograph, Dr. Moorman, with respect to talcum</p> <p>7 powder, specifically, on the right-hand column of</p> <p>8 page 280, it's the third full paragraph down, the IARC</p> <p>9 monograph states (as read):</p> <p>10 "The association between exposure</p> <p>11 to talc, potential or retrograde</p> <p>12 translocation to the ovarian</p> <p>13 epithelium, and the development of</p> <p>14 an ovarian cancer is</p> <p>15 controversial."</p> <p>16 Do you see where I was reading that?</p> <p>17 A. I do see that.</p> <p>18 Q. So in the same monograph where they're</p> <p>19 talking about asbestos and ovarian cancer in general,</p> <p>20 the IARC calls out the issue of talcum powder as a</p> <p>21 controversial association; correct?</p> <p>22 MS. PARFITT: Objection. Form.</p> <p>23 THE WITNESS: That's what it states,</p> <p>24 yes.</p> <p>25</p>	<p>1 A. Yes.</p> <p>2 Q. The IARC has not concluded that the presence</p> <p>3 of asbestos in talc powders renders such powders as</p> <p>4 carcinogenic, has it?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 THE WITNESS: I can't recall if they</p> <p>7 have made that conclusion or not.</p> <p>8 BY MR. JAMES:</p> <p>9 Q. You understand that when the IARC separately</p> <p>10 assessed talcum powders in the other monograph that</p> <p>11 we're talking about, they classified perineal talc use</p> <p>12 as a 2B do you know that?</p> <p>13 MS. PARFITT: And you're referring to</p> <p>14 the 2010 monograph?</p> <p>15 MR. JAMES: Yes, and I think that's</p> <p>16 what I said, and if I didn't, my apologies.</p> <p>17 THE WITNESS: Yes, to be a possible</p> <p>18 carcinogenic.</p> <p>19 BY MR. JAMES:</p> <p>20 Q. Okay. And by designating perineal talc use</p> <p>21 as a 2B, the IARC is not concluding that it is, in</p> <p>22 fact, a carcinogenic; correct?</p> <p>23 A. What they are concluding is that it is a</p> <p>24 possible carcinogen.</p> <p>25 Q. IARC has multiple classifications; correct?</p>
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<p>1 BY MR. JAMES:</p> <p>2 Q. Did you cite that conclusion in your report?</p> <p>3 MS. PARFITT: Objection. Form.</p> <p>4 THE WITNESS: I did not specifically</p> <p>5 cite this, because, you know, again, this was a</p> <p>6 conclusion made IARC 2010, and additional data has</p> <p>7 accumulated. And so I think that we're seeing that if</p> <p>8 they had -- you know, of course, I have no way of</p> <p>9 knowing what they would conclude, but I think that, in</p> <p>10 light of additional evidence that has arisen since the</p> <p>11 time that this report was written, a different</p> <p>12 conclusion could have been reached.</p> <p>13 MR. JAMES: Okay. And I object to the</p> <p>14 nonresponsive portion of that answer.</p> <p>15 BY MR. JAMES:</p> <p>16 Q. And for purposes of the record, Dr. Moorman,</p> <p>17 the monograph that we're looking at here together was</p> <p>18 published in 2012; correct?</p> <p>19 A. That is correct.</p> <p>20 Q. I think that you're probably thinking of the</p> <p>21 other monograph, which is the 2010 monograph; correct?</p> <p>22 When you said 2010?</p> <p>23 A. Well, I was looking at what was stated in</p> <p>24 that paragraph.</p> <p>25 Q. Fair enough. Fair enough.</p>	<p>1 A. That is correct.</p> <p>2 Q. If they characterize -- if they -- if they</p> <p>3 characterize something as a carcinogen, they label it</p> <p>4 as a Group 1; correct?</p> <p>5 A. That is correct.</p> <p>6 Q. If they characterize something as a probable</p> <p>7 carcinogen, they label it a 2A; correct?</p> <p>8 A. That is correct.</p> <p>9 Q. And if they characterize something as a</p> <p>10 possible, it's a 2B; correct?</p> <p>11 A. That is correct.</p> <p>12 Q. And the IARC has settled on 2B with talc --</p> <p>13 and with perineal talc use; correct?</p> <p>14 MS. PARFITT: Objection. Form.</p> <p>15 THE WITNESS: Once again, at the time</p> <p>16 of the report, that's what they decided on.</p> <p>17 BY MR. JAMES:</p> <p>18 Q. The opinions that you're offering in</p> <p>19 litigation in this MDL report are contrary to those</p> <p>20 reached by IARC; correct?</p> <p>21 MS. PARFITT: Objection. Form.</p> <p>22 THE WITNESS: No. I don't think that</p> <p>23 they are contrary. I think possible carcinogen --</p> <p>24 they are not saying it is not a carcinogen; they're</p> <p>25 saying a possible carcinogen.</p>

25 (Pages 94 to 97)

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<p>1 And I -- my report, with the additional 2 information that has been published since the time 3 that this report was done, I think that it strengthens 4 the conclusions. And that's why I felt comfortable 5 saying that it is a cause of ovarian cancer. 6 BY MR. JAMES: 7 Q. And so what you're saying is different than 8 what the IARC said in 2010; correct? 9 MS. PARFITT: Objection. Misstates her 10 testimony. Asked and answered. 11 THE WITNESS: I'm saying that there is 12 additional evidence that has arisen, and it 13 strengthens the -- it strengthens the evidence for the 14 association between talc and ovarian cancer. 15 BY MR. JAMES: 16 Q. And in 2010, IARC did not determine that 17 perineal talc use was carcinogenic; correct? 18 A. They said -- 19 MS. PARFITT: Objection. Misstates 20 testimony. 21 THE WITNESS: -- it was a possible 22 carcinogen. 23 MR. JAMES: I didn't misstate any 24 testimony. I didn't state anything about her 25 testimony. I asked a question.</p>	<p>1 MR. MIZGALA: There's a big difference. 2 MR. JAMES: Let's just move on. 3 MS. PARFITT: I didn't say 4 "peritoneal." That may be what the court reporter -- 5 And, Sophie, the record should reflect that 6 when we are saying -- for the most part, when someone 7 wants to say something, it's "perineal" -- 8 MR. JAMES: May we continue? 9 MS. PARFITT: I appreciate it. Thank 10 you. 11 I just want to help the court reporter out, 12 Scott. I'm sure you want a very clear record. 13 And, James, thank you very much for making 14 sure it is clear. 15 So, Sophie, thank you. When we say 16 "perineal," we mean "perineal." Not your fault at 17 all. 18 Thank you. 19 MR. JAMES: Are we good? 20 MS. PARFITT: We are so good. 21 BY MR. JAMES: 22 Q. In 2010, the IARC declared talc -- perineal 23 talc a 2B; correct? 24 A. That is correct. 25 Q. Okay. In 2010, the evidence that was before</p>
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<p>1 MS. PARFITT: You actually 2 misrepresented her answer in your question. That was 3 my objection. You can go ahead. 4 MR. JAMES: If you'd like to read the 5 realtime, I didn't say anything about what she 6 testified to. I asked a question -- 7 MS. PARFITT: You said, "In 2010" -- 8 (Over-speaking.) 9 MR. JAMES: But if you want to continue 10 to do that all day -- 11 MS. PARFITT: -- "IARC did not 12 determine that peritoneal [sic] talc was carcinogenic; 13 correct?" 14 Just before that, she had said that it was 15 carcinogenic. 16 MR. JAMES: But I wasn't misstating her 17 testimony. 18 MS. PARFITT: Well, when you say that, 19 and she answered the question before that that's not 20 what IARC said, and then you say that is what IARC 21 says, you are misstating her testimony. 22 MR. MIZGALA: It's "perineal," not 23 "peritoneal." 24 MR. JAMES: Let's just move on. If you 25 continue to --</p>	<p>1 the IARC -- was the evidence at that time sufficient 2 for IARC to have said something more than 2B? 3 MS. PARFITT: Objection. Form. 4 THE WITNESS: I'm not quite sure. 5 BY MR. JAMES: 6 Q. You want me to rephrase? 7 A. Yes, if you wouldn't mind. 8 Q. You alluded to evidence that has -- and if 9 I'm misstating your testimony, Ms. Parfitt, please 10 object, because now I actually am talking about your 11 testimony. 12 A. Okay. 13 Q. But you alluded earlier that evidence has 14 developed since the 2010 monograph; correct? 15 A. Right. 16 Q. And so my question is, in your expert 17 assessment in 2010, when the IARC declared perineal 18 talc use to be a 2B, was the evidence at that snapshot 19 in time sufficient to support something more than 2B, 20 less than 2B, or did the IARC get it right? 21 MS. PARFITT: Objection. Form. 22 THE WITNESS: I -- I think that their 23 statement that it is a possible carcinogen -- I don't 24 know if you can -- you know, possible versus probable, 25 it's -- I don't know that there is any checklist to</p>

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<p style="text-align: right;">Page 102</p> <p>1 say this level of evidence would lead it to possible 2 versus probable. 3 And so to say whether or not they got it 4 right, I don't know how to answer that question. 5 I think that they certainly are indicating that there 6 was evidence indicating a problem, and now we have 7 more evidence that strengthens the -- I think there's 8 greater evidence that talc can cause ovarian cancer. 9 BY MR. JAMES: 10 Q. If someone had asked you to assess the body 11 of scientific and medical literature in 2010 on the 12 claim that talcum powder products cause ovarian 13 cancer, would you have opined in 2010 that the 14 evidence was sufficient to state that talcum powder 15 products generally cause ovarian cancer? 16 MS. PARFITT: Objection. Form. 17 THE WITNESS: I think that it is 18 impossible to say with certainty what -- at that point 19 in time what would I have opined? I think that, as we 20 are well aware, the body of literature has continued 21 to grow over time. I think that it has only 22 strengthened over time. At what point would I have 23 been able to opine that talc is a cause of ovarian 24 cancer? I can't pinpoint that exactly. 25</p>	<p style="text-align: right;">Page 104</p> <p>1 MS. PARFITT: Objection to form. 2 THE WITNESS: I -- when I look at some 3 of the studies, there are limitations, as there are 4 with -- I would say, with any study of humans and 5 cancer. 6 One of the things that comes to mind as a 7 possible limitation is that, in the occupational 8 studies, the cohorts are relatively small for looking 9 at cancer outcomes. So in many -- maybe the 10 majority -- of them, they had a few hundred people in 11 the cohort; and, when you looked at the expected 12 versus the observed number of cases, we're talking 13 about a handful of cases. 14 So it might be, you know, two or three 15 observed cases versus .6 expected or something like 16 that. 17 So that is a limitation of all of -- as 18 I recall, all of the occupational cohort studies that 19 the sample cites of the cohort. 20 BY MR. JAMES: 21 Q. Would you also acknowledge that another 22 limitation to that body of literature is the fact that 23 it's in the occupational context? 24 MS. PARFITT: Objection. Form. 25 THE WITNESS: I don't necessarily</p>
<p style="text-align: right;">Page 103</p> <p>1 BY MR. JAMES: 2 Q. And when you say in 2010 IARC declared talc a 3 2B, I think the phrasing that you used was that they 4 were saying that there was, quote, a problem. 5 Is that what you said? 6 A. I think that I said something to that effect. 7 Q. Okay. You understand that the IARC's 8 classification system does have a checklist of sorts 9 to determine if something is a 1, a 2A, or a 2B; 10 correct? Or a 3 and so on and so forth. 11 A. I am not familiar with the exact checklist. 12 Yes. 13 Q. Do you understand that, if IARC declares 14 something a 2B, it's concluding that chance, bias, and 15 confounding cannot be ruled out? Did you know that? 16 A. Again, off the top of my head, I cannot 17 recall exactly what are their -- you know, as you put 18 it, what is their checklist. 19 Q. Returning now back to the body of literature 20 on asbestos and ovarian cancer, you have testified 21 that you have reviewed that body of literature; 22 correct? 23 A. Yes. 24 Q. Do you recognize any limitations to that body 25 of literature?</p>	<p style="text-align: right;">Page 105</p> <p>1 consider that a limitation. That is where people had 2 exposure to this -- to asbestos in an occupational 3 setting. So if you want to look at the health effects 4 of that exposure, that's exactly where you would do 5 the study. 6 BY MR. JAMES: 7 Q. Do you agree that the body of literature in 8 the occupational context, which looks at exposure to 9 asbestos in the occupational setting, is different 10 than the allegation that exposure to contaminated 11 talcum powder products causes ovarian cancer? 12 A. The -- I agree that there is some difference 13 in the exposure, but it's part of the body of 14 literature. It's -- people exposed in this way, they 15 are at increased risk for ovarian cancer. So they may 16 have different levels of exposure, different routes of 17 exposure, but it's all part of the body of literature. 18 Q. You would agree that someone that's exposed 19 to asbestos-containing products in a factory 20 environment for a full workday is experiencing a 21 different level of exposure to someone who is using 22 allegedly contaminated asbestos talcum powder 23 products? 24 MS. PARFITT: Objection. Form. 25</p>

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<p>1 BY MR. JAMES: 2 Q. Let me rephrase that, because I jumbled that 3 up. 4 Would you agree that the level of exposure 5 that someone would experience in the occupational 6 setting to asbestos products is qualitatively 7 different than what Plaintiffs are alleging in this 8 case, which is exposure to talcum powder products that 9 are allegedly contaminated with asbestos? 10 A. I acknowledge that the exposures are 11 different. It's how they are applied -- or, you know, 12 the -- you know, we're talking about exposure to the 13 genital area when we're talking about talcum powder 14 products that may contain asbestos, where we would not 15 expect to have genital exposure of asbestos in an 16 occupational setting. 17 So, yes, there are differences. 18 Q. Do you acknowledge another limitation in the 19 body of literature that IARC looked at to be 20 misclassification? 21 A. In epidemiology, we -- we recognize that 22 there is likely to be misclassification in any 23 epidemiologic study that you do. This is not a 24 situation like with laboratory studies of animals 25 where you can control every exposure, measure it very</p>	<p>1 meta-analysis before; correct? 2 A. I have. 3 Q. You don't have any discussion of the Reid 4 paper in your report; correct? 5 A. I don't -- I don't believe I do. 6 Q. Do you understand that the Reid paper 7 conflicts in part with the claim that asbestos is a 8 cause of ovarian cancer? 9 MS. PARFITT: Objection. 10 THE WITNESS: I know what they -- what 11 these authors concluded. 12 BY MR. JAMES: 13 Q. And if you look with me on page 1294, 14 Dr. Moorman, in the "conclusions" section, you see at 15 the bottom of that paragraph, with the sentence 16 beginning with the word "however" -- it's sort of 17 three-fourths of the way down -- the authors state 18 (as read): 19 "However, the authors of this 20 article suggest that the IARC 21 decision to determine asbestos 22 exposure as a cause of ovarian 23 cancer was premature and not 24 wholly supported by the evidence." 25 Do you see where I read that?</p>
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<p>1 accurately. 2 So some potential misclassification is 3 possible, as it is in any epidemiologic study. 4 Q. And the issue of misclassification has been 5 specifically acknowledged in this body of literature; 6 correct? 7 MS. PARFITT: Objection to form. 8 THE WITNESS: Can you be more specific 9 about which misclassification you're referring to? 10 BY MR. JAMES: 11 Q. Sure. So what I'm referring to is 12 misclassification of disease. 13 Do you -- do you recall that, in this body 14 of literature, there is discussion that, given the 15 small number of cases which you described earlier, 16 misclassification -- the potential for disease 17 misclassification is a limitation to this body of 18 literature? 19 A. I am aware that that is an issue that has 20 been discussed in this literature, yes. 21 MR. JAMES: And I'm going to mark as 22 Exhibit No. 15 the Reid paper. 23 (Exhibit No. 15 was marked for identification.) 24 BY MR. JAMES: 25 Q. And, Dr. Moorman, you've seen this Reid</p>	<p>1 A. I do see that. 2 Q. Okay. And so you acknowledge here that the 3 authors of this paper have called into question the 4 IARC decision; correct? 5 MS. PARFITT: Objection. Form. 6 THE WITNESS: I see what they have 7 stated here, that -- 8 BY MR. JAMES: 9 Q. And -- 10 A. -- that is their opinion, yes. 11 Q. Excuse me, Doctor. My apologies. 12 A. Yes. 13 Q. And, again, this paper is assessing the 14 IARC's conclusion about asbestos and ovarian cancer in 15 general; correct? 16 MS. PARFITT: Objection. Form. 17 BY MR. JAMES: 18 Q. It's not -- this article isn't pertaining to 19 the issue of alleged asbestos contamination in talcum 20 powder products, is it? 21 A. Right. This is focused just on asbestos and 22 ovarian cancer. 23 Q. And if you look at the bottom of that -- the 24 very last sentence in that paragraph, you see where 25 the authors there discuss the potential problem of</p>

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<p>1 misclassification?</p> <p>2 A. I'm sorry, where are you?</p> <p>3 Q. It's the very last sentence, Doctor.</p> <p>4 A. Yes, I see what is written there.</p> <p>5 Q. So this article conflicts with your</p> <p>6 litigation opinion; correct?</p> <p>7 MS. PARFITT: Objection. Form.</p> <p>8 THE WITNESS: This reflects the opinion</p> <p>9 of these authors. There was another meta-analysis of</p> <p>10 asbestos and ovarian cancer that I believe was</p> <p>11 published in the same year. And as I recall, the</p> <p>12 conclusions of those authors, while acknowledging</p> <p>13 potential misclassification of disease, they felt like</p> <p>14 the evidence was adequate to rule that out as a</p> <p>15 possible source of bias that would explain the</p> <p>16 association that was observed.</p> <p>17 BY MR. JAMES:</p> <p>18 Q. And you're speaking of the Camargo article,</p> <p>19 I believe?</p> <p>20 A. Yes.</p> <p>21 Q. And have you separately assessed the issue of</p> <p>22 misclassification and whether, in your mind, that</p> <p>23 presents a significant enough problem to call into</p> <p>24 question the IARC conclusions?</p> <p>25 MS. PARFITT: Objection. Form.</p>	<p>1 Q. Did you review those articles?</p> <p>2 A. I did look at them, and as I recall, almost</p> <p>3 all of those -- the miners and -- almost all of the</p> <p>4 miners, and probably the millers, they were focusing</p> <p>5 primarily on males who were the people who were mostly</p> <p>6 involved in that type of work.</p> <p>7 Q. You would agree with me that if talcum</p> <p>8 powder, that is used in cosmetic talc products, is, in</p> <p>9 fact, contaminated with asbestos, then you would</p> <p>10 expect to see increased cancer incidence rates, for</p> <p>11 example, of mesothelioma, in cosmetic talc miners and</p> <p>12 millers; correct?</p> <p>13 MS. PARFITT: Objection. Form.</p> <p>14 THE WITNESS: I wouldn't be surprised</p> <p>15 to see that, yes.</p> <p>16 BY MR. JAMES:</p> <p>17 Q. And did you know that that body of literature</p> <p>18 reports no increased cancer incidence in talc miners</p> <p>19 and millers?</p> <p>20 A. It has been a while since I have looked at</p> <p>21 those papers, so I don't remember exactly what they</p> <p>22 reported.</p> <p>23 Q. And those papers are not discussed in your</p> <p>24 report; correct?</p> <p>25 A. Once again, I was focusing primarily on</p>
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<p>1 THE WITNESS: Let me read your...</p> <p>2 I believe that I was convinced by the</p> <p>3 information presented in the Camargo article that</p> <p>4 I don't think that misclassification was enough of a</p> <p>5 problem to change the conclusion.</p> <p>6 BY MR. JAMES:</p> <p>7 Q. Are you familiar with -- did you undertake a</p> <p>8 Bradford Hill analysis of the literature on asbestos</p> <p>9 and ovarian cancer to reach the conclusion that</p> <p>10 asbestos is a cause of ovarian cancer?</p> <p>11 A. I didn't -- did not do the Bradford Hill</p> <p>12 analysis as I did with the talcum powder products and</p> <p>13 ovarian cancer. I felt like it was pretty well</p> <p>14 accepted.</p> <p>15 Q. Did you consider a body of literature</p> <p>16 commonly referred to as the "miners and millers</p> <p>17 studies"?</p> <p>18 A. Please -- I'm sorry. When you talk about the</p> <p>19 miners and millers studies, I'm not sure that I'm on</p> <p>20 the same page with you.</p> <p>21 Q. Are you familiar -- are you aware of the fact</p> <p>22 that there's a body of literature that has looked at</p> <p>23 cancer incidence rates in miners and millers of talc?</p> <p>24 A. Yes, I am aware of some of those articles.</p> <p>25 Yes.</p>	<p>1 ovarian cancer. And as many of these were on male</p> <p>2 subjects, I had looked at them, but they were of</p> <p>3 somewhat lesser importance to my review.</p> <p>4 Q. If --</p> <p>5 MS. PARFITT: I don't want to</p> <p>6 interrupt, and maybe a few follow-up questions. We're</p> <p>7 probably into about an hour and 20 minutes or so. But</p> <p>8 I don't want to interrupt your flow either.</p> <p>9 MR. JAMES: I can finish up in a few,</p> <p>10 or if you need a break now, we can take it now.</p> <p>11 THE WITNESS: Let's finish up in a few.</p> <p>12 MR. JAMES: And when I say "finish up,"</p> <p>13 I just mean this line. I apologize for that. That</p> <p>14 was misleading, I think.</p> <p>15 Sure. Give me a couple more, and then we'll</p> <p>16 take a break.</p> <p>17 THE WITNESS: Yeah, we can go a few</p> <p>18 more minutes.</p> <p>19 MS. PARFITT: Thank you, Scott.</p> <p>20 BY MR. JAMES:</p> <p>21 Q. If asbestos-contaminated talcum powder</p> <p>22 products have existed on the market for some period of</p> <p>23 time, wouldn't you expect to find higher incidence</p> <p>24 rates of other cancers of talcum powder users?</p> <p>25 MS. PARFITT: Objection. Form.</p>

29 (Pages 110 to 113)

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<p style="text-align: right;">Page 114</p> <p>1 THE WITNESS: It depends. 2 BY MR. JAMES: 3 Q. For example -- oh, I'm sorry. I thought you 4 were done. 5 A. I am done. Go ahead. 6 Q. For example, if asbestos has contaminated 7 talcum powder products for some period of time, 8 wouldn't you expect to see higher rates of 9 mesothelioma in users of cosmetic talcum powder 10 products? 11 A. You know, mesothelioma is an exceedingly rare 12 cancer, and I don't know -- I don't know to what 13 extent it has been -- talcum powder products -- 14 cosmetic talcum powder products has been examined as a 15 risk factor for that. 16 Q. Are you aware of any data showing that users 17 of cosmetic talcum powder products are at greater risk 18 of mesothelioma, asbestosis, or any other 19 asbestos-related diseases? 20 MS. PARFITT: Objection. Form. 21 THE WITNESS: I can't think of that 22 data right offhand, no. 23 MR. JAMES: Okay. And how about now 24 for a break? 25 THE WITNESS: Okay.</p>	<p style="text-align: right;">Page 116</p> <p>1 MS. PARFITT: Objection. Form. 2 THE WITNESS: I considered it as part 3 of the constituents of the talcum powder products. My 4 overall opinion is based on exposure to talcum powder 5 products and whatever constituents are in there, 6 including the fibrous talc. 7 BY MR. JAMES: 8 Q. Given that you have opined in your MDL report 9 for the first time on fibrous talc and did not provide 10 that opinion in the Ingham case, can you tell me what 11 you're basing your opinion on with regard to the 12 fibrous talc? 13 MS. PARFITT: Objection. 14 Hey, Scott, if I can ask -- I'm sorry, it 15 isn't rolling. Is there some reason? I don't want to 16 interrupt. We'll deal with it. 17 THE COURT REPORTER: I can come over 18 and do it, but we'll have to go off. 19 MS. PARFITT: Sorry about that. 20 THE VIDEOGRAPHER: Going off the record 21 at 12:40 p.m. 22 (Off the record.) 23 THE VIDEOGRAPHER: Back on record at 24 12:41 p.m. 25</p>
<p style="text-align: right;">Page 115</p> <p>1 MS. PARFITT: Thank you. 2 THE VIDEOGRAPHER: Going off record at 3 11:45 a.m. 4 (Recess taken from 11:45 a.m. to 12:39 p.m.) 5 THE VIDEOGRAPHER: Back on record at 6 12:39 p.m. 7 BY MR. JAMES: 8 Q. Dr. Moorman, you include in your MDL report 9 references to "talc occurring in the fibrous habit." 10 Do you recall referring to that in your 11 report? 12 A. Yes, I do. 13 Q. That terminology is new to the MDL for you, 14 isn't it? 15 MS. PARFITT: Objection. Form. 16 BY MR. JAMES: 17 Q. I'll clarify. 18 A. Please. Please do. 19 Q. You did not -- in your Ingham testimony, 20 where you provided your opinions in the Ingham case, 21 you did not refer to "fibrous talc," did you? 22 A. No, I don't believe I did. 23 Q. So that -- sorry. 24 So that's a new component of your opinion in 25 the MDL?</p>	<p style="text-align: right;">Page 117</p> <p>1 BY MR. JAMES: 2 Q. Dr. Moorman, before the quick break -- I'll 3 just restate the question. 4 A. Okay. 5 Q. So what do you base your opinions on with 6 regard to fibrous talc? 7 A. Okay. My opinion, I guess, is -- again, it's 8 always been based on the constituents of the talcum 9 powder products. And so maybe clarifying based on 10 maybe further reading on the constituents of, like, 11 asbestiform talc, that this again contributes to the 12 biological plausibility of it, that this is another 13 potential constituent of the talcum powder product 14 that could contribute to ovarian cancer risk. 15 Q. So one component of your opinion is that 16 there is fibrous talc in talcum powder products; 17 correct? 18 A. Yes. 19 Q. Okay. And given that that is a new opinion, 20 I am attempting to source the bases for that opinion. 21 Are the opinions that you have about the 22 presence of fibrous talc in talcum powder products 23 based upon the same materials that you rely on for 24 your opinions about the presence of asbestos in talcum 25 powder products?</p>

30 (Pages 114 to 117)

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<p>1 MS. PARFITT: Objection. Form. As far 2 as a new opinion. 3 THE WITNESS: I'm sorry, let me read 4 that. 5 So my opinions about the presence of fibrous 6 talc in talcum powder products is based on some of the 7 same materials that have done analyses of talcum 8 powder products, yeah. 9 BY MR. JAMES: 10 Q. Would that include the Longo -- Dr. Longo 11 litigation testing? 12 A. I believe that he did make some mention of 13 that in his report, yes. 14 Q. And other -- would that include other 15 litigation reports that you reviewed? 16 MS. PARFITT: Objection. Form. 17 THE WITNESS: I'm -- precisely where 18 the information came from, that there is fibrous talc 19 in talcum powder products, I -- I don't recall exactly 20 where -- where I gleaned that information. 21 BY MR. JAMES: 22 Q. And did you -- did you ask counsel if there 23 was any information provided by Johnson & Johnson in 24 the talc litigation rebutting the claim that there's 25 fibrous talc present in the products?</p>	<p>1 BY MR. JAMES: 2 Q. Would you defer to others with regard to the 3 question of whether heavy metals are in the talcum 4 powder products? 5 A. I -- by deferring to others, okay, I clearly 6 do not do the analyses of those -- of those -- those 7 types of analyses myself, so I am relying on a report. 8 In this case, it was a report done by Dr. Crowley. 9 Q. Just to clarify, and Ms. Parfitt can correct 10 me if I'm wrong, but when you refer to Dr. Crowley's 11 report, are you referring to Dr. Crowley's report 12 about fragrances? 13 A. And I believe that it was not just 14 fragrances, but it was a number of substances that he 15 analyzed in that -- that he addressed in his analysis. 16 Q. Did you do any independent searching for 17 materials or scientific literature on the allegation 18 that heavy metals in cosmetic talc powders cause 19 ovarian cancer? 20 MS. PARFITT: Objection. 21 THE WITNESS: Okay. I'm reading your 22 question again. 23 No. I -- the -- what I looked at in regards 24 to heavy metals -- again, we have this report 25 indicating that these can be found in some talcum</p>
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<p>1 MS. PARFITT: Objection. Form. 2 THE WITNESS: No, I did not 3 specifically ask them for that information. 4 BY MR. JAMES: 5 Q. Have you relied on any epidemiology 6 substantiating a claim that fibrous talc is 7 carcinogenic? 8 A. I am not aware of any epidemiologic 9 literature that specifically addressed that question. 10 Q. Turning to your opinions on heavy metals, 11 Dr. Moorman, you have opined in your report about 12 chromium, nickel, and cobalt; correct? 13 A. Yes, I have. 14 Q. Yet your opinions in the MDL report about the 15 alleged presence of chromium, nickel, and cobalt in 16 talcum powder products is new in the sense that you 17 did not express that opinion in the Ingham case; 18 correct? 19 MS. PARFITT: Objection. Misstates her 20 testimony -- our testimony. 21 THE WITNESS: I think the gist of my 22 opinions are based on talcum powder products and 23 whatever constituents are in there; so talc, asbestos, 24 any fragrances or other contaminants that may be in 25 there. So it's based on the product.</p>	<p>1 powder products, and then again we have data 2 indicating that these heavy metals can cause certain 3 types of cancer. 4 So it contributes to the biological 5 plausibility that there are substances in the talcum 6 powder products that could lead to cancer. 7 BY MR. JAMES: 8 Q. With regard to opinions about the presence of 9 heavy metals in talcum powder products, did you ask to 10 see any information or materials presented in the talc 11 litigation by Johnson & Johnson as to that claim? 12 A. No, I did not. 13 Q. Did you do any separate analysis of the 14 talcum powder products to determine the presence of 15 heavy metals in these products? 16 A. I did not do any analyses of talcum powder 17 products. 18 Q. Do you have any knowledge concerning the 19 testing that is performed by Johnson & Johnson and 20 third parties with respect to constituent elements in 21 the products? 22 A. No. This is outside my area of expertise. 23 Q. Do you have any information about allowable 24 levels of constituent elements in the talcum powder 25 products?</p>

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<p>1 A. No, I do not.</p> <p>2 Q. Do you have any basis to believe that if</p> <p>3 talcum powder products exceeded allowable levels for</p> <p>4 constituent elements, that those products went to</p> <p>5 market?</p> <p>6 MS. PARFITT: Objection. Form.</p> <p>7 THE WITNESS: No, I -- I don't have any</p> <p>8 information in that regard.</p> <p>9 BY MR. JAMES:</p> <p>10 Q. Okay. Turning to -- with -- to your opinion</p> <p>11 on -- strike that.</p> <p>12 Do you hold the independent opinion that</p> <p>13 cadmium, chromium, and cobalt cause ovarian cancer?</p> <p>14 MS. PARFITT: Objection. Form.</p> <p>15 THE WITNESS: I do -- I am not aware of</p> <p>16 papers that have directly addressed those metals in</p> <p>17 relation to ovarian cancer risk. I am basing it more</p> <p>18 on the conclusions from IARC that they do have</p> <p>19 carcinogenic potential.</p> <p>20 BY MR. JAMES:</p> <p>21 Q. And is the same true for nickel?</p> <p>22 A. Yes.</p> <p>23 Q. With regard to the alleged carcinogenicity of</p> <p>24 the constituent metal elements that you've identified</p> <p>25 in your report, did you consider anything other than</p>	<p>1 THE WITNESS: I -- I think that we do</p> <p>2 not have the data to specifically address that</p> <p>3 question specifically in regard to ovarian cancer.</p> <p>4 BY MR. JAMES:</p> <p>5 Q. With regard to the opinions you've expressed</p> <p>6 as to fragrances, is the sole basis of those opinions</p> <p>7 the value of work?</p> <p>8 A. That's the only document that I referred to.</p> <p>9 Q. And you understand --</p> <p>10 MR. JAMES: Ms. Parfitt, is it</p> <p>11 Dr. Crowley?</p> <p>12 MS. PARFITT: Dr. Crowley.</p> <p>13 BY MR. JAMES:</p> <p>14 Q. Okay. Do you understand that Dr. Crowley is</p> <p>15 a paid expert in this litigation for the Plaintiffs?</p> <p>16 A. I do understand that.</p> <p>17 Q. Do you know if Dr. Crowley conducted any sort</p> <p>18 of risk assessment with regard to his calculations?</p> <p>19 A. I do not know that.</p> <p>20 Q. If Johnson & Johnson talcum powder products</p> <p>21 were not contaminated with asbestos, if you would</p> <p>22 accept that proposition from me, would you still hold</p> <p>23 the opinion that talcum powder products are a general</p> <p>24 cause of ovarian cancer?</p> <p>25 MS. PARFITT: Objection. Form.</p>
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<p>1 the IARC monograph that you cited?</p> <p>2 A. No, I did not.</p> <p>3 Q. Did the IARC monograph that you cited include</p> <p>4 any assertion that the presence of these metals in</p> <p>5 talcum powders rendered those powders carcinogenic?</p> <p>6 A. I do not believe so.</p> <p>7 Q. Did the IARC 2010 monograph on talc include</p> <p>8 any assertion that the presence of heavy metals in</p> <p>9 those powders supports the 2B conclusion?</p> <p>10 MS. PARFITT: Objection. Form.</p> <p>11 THE WITNESS: I don't recall any</p> <p>12 mention of heavy metals in that monograph.</p> <p>13 BY MR. JAMES:</p> <p>14 Q. Returning back to fragrances, in your MDL</p> <p>15 report, you refer to a report by Crowley. Did I say</p> <p>16 that right?</p> <p>17 A. I've never met the man, so I don't know how</p> <p>18 it's pronounced, but yes, that's what I said.</p> <p>19 Q. And that's the report you identified for the</p> <p>20 basis of your fragrance opinions; correct?</p> <p>21 A. Yes.</p> <p>22 Q. Do you have -- do you hold the independent</p> <p>23 opinion that the fragrance ingredients in talcum</p> <p>24 powder products renders those products carcinogenic?</p> <p>25 MS. PARFITT: Objection.</p>	<p>1 You can answer.</p> <p>2 THE WITNESS: Okay. The opinion</p> <p>3 I formed is based primarily on the epidemiologic data;</p> <p>4 and the epidemiologic data is based on talcum powder</p> <p>5 products, whatever is contained in them. And in study</p> <p>6 after study, we see increased risk for ovarian cancer.</p> <p>7 So whatever is contained in the talcum powder products</p> <p>8 leads me to conclude that it can cause ovarian cancer.</p> <p>9 BY MR. JAMES:</p> <p>10 Q. And just to make sure that I understand your</p> <p>11 answer --</p> <p>12 A. Yes.</p> <p>13 Q. -- if the talcum powder products were not</p> <p>14 contaminated with asbestos, would you still reach the</p> <p>15 general cause opinion that you've offered in this</p> <p>16 case?</p> <p>17 MS. PARFITT: Objection. Form.</p> <p>18 THE WITNESS: I am -- I think that I've</p> <p>19 answered the question that it's based on talcum powder</p> <p>20 products, whatever is contained them -- in them. If</p> <p>21 it is shown that there is no asbestos, that doesn't</p> <p>22 change the fact that these dozens of epidemiologic</p> <p>23 studies have led to the conclusion of increased risk.</p> <p>24 BY MR. JAMES:</p> <p>25 Q. And does that same answer hold true if</p>

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<p>1 I asked you the same question with respect to heavy 2 metals, fibrous talc, and fragrance ingredients? 3 MS. PARFITT: Objection. Form. 4 THE WITNESS: Yes. I am basing my 5 opinion on the use of talcum powder products and 6 whatever are -- whatever their constituents are. 7 BY MR. JAMES: 8 Q. As a professional epidemiologist -- is that a 9 fair way to say it? 10 A. Yes. 11 Q. Okay. As a professional epidemiologist, part 12 of your day-in, day-out work is to look at literature 13 on purported associations and make conclusions about 14 the strengths or weaknesses of that literature; 15 correct? 16 A. Yes. 17 Q. And you have done that before you were 18 brought into the talc litigation on a variety of 19 different exposures or other things evaluated for 20 associations; correct? 21 A. That is correct. 22 Q. And setting aside the issue of talcum powder 23 products, have you ever before, in assessing other 24 exposures or other associations, relied upon company 25 documents to reach your conclusions?</p>	<p>1 BY MR. JAMES: 2 Q. On page 4 of your -- actually, it's page 5 of 3 your report, Dr. Moorman. You refer on the top of 4 that page, in the first full paragraph, to the 5 Schildkraut 2016 study; correct? 6 A. First paragraph? Yes, that is correct. 7 Q. And you say in that paragraph -- and if 8 you're looking at the same paragraph as I am -- you 9 say there that (as read): 10 "This was the first study of talc 11 use and ovarian cancer focused 12 exclusively on African-American 13 women." 14 Correct? 15 A. Yes, I do. 16 Q. And to be clear, Dr. Moorman, that study did 17 not look exclusively at talc use, did it? 18 A. No. The purpose of the African American 19 cancer epidemiology study was to look at the 20 epidemiology of ovarian cancer in African American 21 broadly. So we've looked at a number of exposures. 22 Q. And specific to the issue of powder, the 23 Schildkraut 2016 study -- and I guess is the 24 underlying study, the AACES -- looks at body powder, 25 not talc per se; correct?</p>
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<p>1 A. I -- I'm trying to think. 2 We have -- my colleagues and I have 3 published systematic reviews of oral contraceptive use 4 and ovarian cancer and other cancer risk. And as part 5 of that procedure -- this was through the Agency on 6 Healthcare Research and Quality, or AHRQ -- and as 7 part of that procedure trying to ensure that we have 8 all relevant documents, I believe that there was an 9 effort to see if there were any company document 10 studies that would be relevant to that systematic 11 review. 12 Q. What about any internal company testing 13 documents? Have you ever looked at any internal 14 company testing documents in assessing any association 15 that you've considered throughout your career? 16 A. No -- 17 MS. PARFITT: Objection. 18 THE WITNESS: -- I did not. 19 BY MR. JAMES: 20 Q. Have you ever considered any paid litigation 21 expert reports in assessing any other association that 22 you've looked at through your career? 23 MS. PARFITT: Objection. Form. 24 THE WITNESS: I -- I can't think of 25 another instance where I have done that.</p>	<p>1 A. That was how the question was asked in the 2 questionnaire, yes. 3 Q. Okay. And so the statements in your report 4 that state that the study looked at talc powder should 5 be clarified; correct? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: I think to be absolutely 8 precise, we should have -- I should have said body 9 powder. But based on other literature, most body 10 powder use is talcum powder product use. So I agree, 11 I could have been more precise in my language there. 12 BY MR. JAMES: 13 Q. And you understand body powders are made up 14 of a variety of constituents; correct? 15 A. Yes. 16 Q. There are baby powders that are made of 17 things other than talc; correct? 18 A. I believe so, that there are cornstarch 19 powders as well. 20 Q. And there are deodorizing powders that are 21 made of things other than talc; correct? 22 A. I believe so, yes. 23 Q. And you know cornstarch, if there's a baby 24 powder made of cornstarch, that product does not 25 contain talc; correct?</p>

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<p>1 A. Yes.</p> <p>2 Q. Or -- I should clarify.</p> <p>3 If the version of the baby powder one is</p> <p>4 purchasing is labeled as a cornstarch product, it's</p> <p>5 cornstarch, not talc; correct?</p> <p>6 A. That is correct.</p> <p>7 Q. So the study participants in this study are</p> <p>8 not limited to talc users; correct?</p> <p>9 A. That is correct.</p> <p>10 Q. You also say in the report, in conjunction</p> <p>11 with these statements, that the study found a high</p> <p>12 prevalence of talc use; correct?</p> <p>13 A. Yes.</p> <p>14 Q. And we're looking at the same paragraph,</p> <p>15 Dr. Moorman. And, again, to be clear, the study</p> <p>16 didn't find that. The study, instead, found a high</p> <p>17 prevalence of powder use; correct?</p> <p>18 MS. PARFITT: Objection.</p> <p>19 THE WITNESS: Again, once I -- as I</p> <p>20 acknowledged earlier, I could have been more precise</p> <p>21 in the language, that it's -- I think that it -- based</p> <p>22 on our knowledge of the sales and other studies that</p> <p>23 have specifically reported on the types of powder use,</p> <p>24 the majority of the powder use would have been talc.</p> <p>25</p>	<p>1 anywhere else in your report, that for any genital use</p> <p>2 of body powder with an interview date before 2014, the</p> <p>3 results were not statistically significant; correct?</p> <p>4 MS. PARFITT: Objection.</p> <p>5 THE WITNESS: If you would give me just</p> <p>6 a moment to look through the report, I'd like to</p> <p>7 verify how I addressed that.</p> <p>8 I -- on page 23, I acknowledged that there</p> <p>9 was an attenuation of the odds ratio when comparing</p> <p>10 the women who were interviewed in the later time frame</p> <p>11 than in the earlier time frame.</p> <p>12 BY MR. JAMES:</p> <p>13 Q. Okay. And I'm looking at where you're</p> <p>14 looking, I believe, and it's the middle paragraph on</p> <p>15 page 23; correct?</p> <p>16 A. That is correct.</p> <p>17 Q. And there you say (as read):</p> <p>18 "The fact that the association was</p> <p>19 attenuated but not eliminated when</p> <p>20 considering the full study</p> <p>21 population suggested that the</p> <p>22 association was not due entirely</p> <p>23 to recall bias."</p> <p>24 Did I read that correctly?</p> <p>25 A. That is correct.</p>
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<p>1 BY MR. JAMES:</p> <p>2 Q. You're not offering opinions on the MDL</p> <p>3 litigation about cornstarch, are you?</p> <p>4 A. No, I am not.</p> <p>5 Q. And you understand that the body of</p> <p>6 epidemiological literature that has developed over the</p> <p>7 last several decades has included findings looking at</p> <p>8 talc powders versus cornstarch powders versus non-talc</p> <p>9 powders; correct?</p> <p>10 A. Some studies, yes, have looked at the</p> <p>11 different powders.</p> <p>12 Q. And your -- the Schildkraut 2016 study didn't</p> <p>13 undertake the effort to make that distinction, did it?</p> <p>14 MS. PARFITT: Objection.</p> <p>15 THE WITNESS: I've already acknowledged</p> <p>16 that the question in the questionnaire just asked</p> <p>17 about body powder use.</p> <p>18 BY MR. JAMES:</p> <p>19 Q. You state that this study found a</p> <p>20 statistically significant increase for risk among talc</p> <p>21 users; right?</p> <p>22 A. Yes. We're in the same paragraph. Right?</p> <p>23 Q. Yes, Doctor. Thank you.</p> <p>24 A. Yes.</p> <p>25 Q. But you did not know in this paragraph, or</p>	<p>1 Q. Okay. And, again, here you do not report --</p> <p>2 let me start over.</p> <p>3 The association for talc users before 2014</p> <p>4 date was not statistically significant; correct?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 THE WITNESS: Yes. The -- the odds</p> <p>7 ratio was elevated but not statistically significant.</p> <p>8 BY MR. JAMES:</p> <p>9 Q. And you don't call that out in your report,</p> <p>10 do you?</p> <p>11 MS. PARFITT: Objection. Form.</p> <p>12 THE WITNESS: No. It's as it's</p> <p>13 written.</p> <p>14 BY MR. JAMES:</p> <p>15 Q. And as it's written, it says, "The</p> <p>16 association was attenuated but not eliminated."</p> <p>17 That's the wording you used; correct?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. But if the association is not</p> <p>20 statistically significant, would you still refer to</p> <p>21 that association as attenuated and not eliminated? Is</p> <p>22 that the proper way to refer to it?</p> <p>23 A. If the association was eliminated, if there</p> <p>24 was no association, we would have had an odds ratio of</p> <p>25 1. We have an odds ratio of 1.19.</p>

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<p>1 It is -- I acknowledge that it was not 2 statistically significant, but it was not eliminated. 3 It was attenuated. I think that my statement in my 4 report is accurate. 5 Q. So for any epidemiologic study that has an 6 odds ratio that crosses 1 but is reported to be above 7 1 with the odds ratio crossing 1 -- do you understand 8 what I'm asking? -- would you refer to that as an 9 association, an null association, a not statistically 10 significant association? What terminology would you 11 use? 12 A. I would refer to it as a non-statistically 13 significant association. If the data show 19 percent 14 increased risk, it's not statistically significant. 15 Q. And by saying that, what you're saying is 16 that the odds ratio that -- could fall with any -- 17 within the range identified; correct? 18 MS. PARFITT: Objection. Form. 19 THE WITNESS: The -- when you report a 20 95 percent confidence interval, it gives a range of 21 values which is statistically compatible with what you 22 found. Like, if the study were repeated again with 23 other samples, you might find an odds ratio that was a 24 bit higher or a bit lower. 25 But I think that it's very important to make</p>	<p>1 with respect to talc? 2 A. If you -- I know you have it right in front 3 of you. So if I could see it, so I could report it 4 accurately. I think I know what I found, but that was 5 paper that was done ten years ago. 6 MR. JAMES: Okay. And, Dr. Moorman, 7 I'm marking as Exhibit 16 a paper entitled "Ovarian 8 Cancer Risk Factors in African-American and White 9 Women." 10 I'm handing you two copies to pass along. 11 (Exhibit No. 16 was marked for identification.) 12 THE WITNESS: Okay. So we reported on 13 talc use for white women and for African-American 14 women. Neither association was statistically 15 significant, again, particularly for the African 16 American, which can be a reflection of the relatively 17 small sample size for African-American women. It was 18 an odds ratio of 1.19; in the white women, it was 19 1.04. 20 BY MR. JAMES: 21 Q. And those two associations reported in your 22 paper in 2009 are not reported in your report, are 23 they? 24 A. I did not -- I do not believe that I reported 25 those specific odds ratios. Data from the</p>
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<p>1 the distinction between no association and no 2 statistically significant association. 3 BY MR. JAMES: 4 Q. But you didn't make that distinction in your 5 report? 6 MS. PARFITT: Objection. 7 THE WITNESS: You've asked the 8 question, and I've acknowledged that I did not address 9 statistical significance in that sentence. 10 BY MR. JAMES: 11 Q. On the same page of your report, if we go 12 back to page 5, you refer to a 2009 paper entitled 13 "Ovarian Cancer Risk Factors in African-American and 14 White Women"; correct? 15 A. Let me get to page 5. Which paragraph are 16 you -- 17 Q. So it's the second paragraph. In fact, you 18 refer to it here as the North Carolina Ovarian Cancer 19 Study; correct? 20 A. Right. Right. Okay. Yes. 21 Q. My apologies. I -- with -- in conjunction 22 that study, you published a paper in 2009; correct? 23 A. Right. Talc was not the primary focus of it, 24 but it was one of the risk factors that we looked at. 25 Q. And do you recall the results of that study</p>	<p>1 North Carolina ovarian cancer study was included in 2 the meta-analyses that I did describe. 3 Q. And with respect to odds ratio of 1.04 for 4 white women -- do you see that? Are we looking at the 5 same table together? Table 2? 6 A. Yes. 7 Q. Okay. And the 1.04 association there is very 8 close to the null; correct? 9 MS. PARFITT: Objection. Form. 10 THE WITNESS: Yes, it's close to 1. 11 BY MR. JAMES: 12 Q. And it has the odds ratio that crosses 1; 13 correct? The odds ratio range? Is that a fair way to 14 say it? 15 A. No. 16 Q. Okay. Tell me how to say it. 17 A. The 95 percent confidence interval -- 18 Q. That's right. 19 A. -- does cross 1. 20 Q. So we have the 1.04 with the CI crossing 1; 21 correct? 22 A. Yes. 23 Q. Would you refer to the 1.04 as an association 24 that is attenuated but not eliminated? 25 A. Well, first of all, I would not refer to it</p>

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<p>1 as attenuated because that implies that there's a 2 comparison with something else; and in the other 3 paper, it was comparing the full study population to a 4 subset. So I would never refer to this as attenuated. 5 This is what was shown in this particular 6 study. It's an odds ratio of 1.04. It's very close 7 to 1. 8 Q. Fair enough. And fair point about 9 attenuated. 10 Would you refer to a 1.04 with a CI that 11 crosses 1 as a positive association, as professional 12 epidemiologist? 13 A. When I would look at that, I would say that 14 there's little evidence of an association, very close 15 to 1, in this study population -- in this study. 16 Q. You've also published another study coming 17 out of the North Carolina Ovarian Cancer Study; 18 correct? 19 A. I have published quite a few papers that came 20 out of the North Carolina Ovarian Cancer Study. 21 Q. And do you recall publishing a paper in 2010 22 entitled "Primary peritoneal and ovarian cancers: An 23 epidemiologic comparative analysis"? 24 A. I was a coauthor on that paper, yes. 25 Q. Okay. And is this paper discussed in your</p>	<p>1 A. Yes, that's what's reported there based on a 2 quite small sample size. 3 Q. And, again, both of these associations are 4 not statistically significant; correct? 5 A. That is correct. 6 Q. And also I see over here to the left, the 7 category listed here is labeled "Talc use"; correct? 8 A. Yes. 9 Q. So this paper looks specifically at talcum 10 powders; is that right? 11 A. I -- I believe that, in that questionnaire, 12 it was specifically asking about talc use. 13 Q. And, again, the results of this study are not 14 reported in your report; correct? 15 A. As I said before when you asked that, the 16 data from the North Carolina Ovarian Cancer are 17 included in the Terry paper that combined data from 18 multiple studies. 19 Q. On page 11 of your report, Dr. Moorman, you 20 state, in the -- I guess it's the second paragraph 21 down from the top, starting with the "it is important" 22 language. 23 A. Mm-hmm. 24 Q. Okay. And if you look down to the second 25 sentence, you note there that (as read):</p>
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<p>1 expert report at all? 2 A. I don't think that I specifically addressed 3 it. Again, the data from the North Carolina Ovarian 4 Cancer Study was included in the Terry analysis -- 5 MR. JAMES: And I've marked the study 6 that I just referenced as Exhibit No. 17. I'm going 7 to hand you two copies. 8 (Exhibit No. 17 was marked for identification.) 9 BY MR. JAMES: 10 Q. And, Dr. Moorman, if we turn to page 995, 11 there is a Table 2 continued onto page. And if you 12 look down, this paper does report odds ratios for talc 13 use; correct? 14 A. Yes, it does. 15 Q. And for -- if you look over to the right, all 16 the way to the right, you see that you've reported a 17 1.15 not statistically significant association for 18 serous invasive ovarian cancer; correct? 19 A. That's correct. 20 Q. And that's with a CI that crosses 1; correct? 21 A. That is correct. 22 Q. And if you look to the left of that, you've 23 reported here a .76 odds ratio for the relationship 24 between talc use and primary peritoneal cancer; 25 correct?</p>	<p>1 "It is not unusual for scientists 2 and epidemiologists to weigh the 3 Hill factors differently in 4 reaching the conclusion." 5 Correct? 6 A. Yes, I state that. 7 Q. And then in the next sentence, you go on to 8 provide examples of that; correct? 9 A. Correct. 10 Q. And you note there (as read): 11 "The evidence that cigarette 12 smoking causes lung cancer or 13 asbestos causes lung disease." 14 Right? 15 A. Yes. 16 Q. And those are the examples that you're 17 providing to support the prior sentence that 18 epidemiologists can sometimes weigh things 19 differently; is that right? 20 A. I give that as an example, yes. 21 Q. For the two examples that you've provided 22 there, has the medical and scientific community 23 accepted that smoking causes lung cancer and that 24 asbestos causes lung disease? 25 A. I think that, yes, that is true. Now, the</p>

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<p style="text-align: right;">Page 142</p> <p>1 point that I am making here is that some scientists, 2 especially in the early years when the data were 3 accumulating related to smoking and lung cancer, some 4 people weighted the evidence differently. 5 For example, some of the studies looked at 6 whether people reported whether or not they inhaled or 7 not, and some funny results were observed there. And 8 some scientists thought that was really important 9 evidence against an association, whereas others 10 thought it was -- it was not to be regarded very 11 seriously. 12 Q. Do you regard the body of evidence on smoking 13 and asbestos to be equivalent to the body of evidence 14 on talc and ovarian cancer with regard to evaluating 15 cause? 16 MS. PARFITT: Objection. 17 THE WITNESS: Could you clarify what 18 you mean by "equivalent"? 19 BY MR. JAMES: 20 Q. Sure. By providing these two examples 21 here -- first, the smoking example, and second, the 22 asbestos example -- are you suggesting that the body 23 of evidence to support the causal conclusion with 24 respect to asbestos and smoking is qualitatively 25 and/or quantitatively the same or similar to the body</p>	<p style="text-align: right;">Page 144</p> <p>1 that the criteria that I applied to come to a 2 conclusion of causality are based on strong data. 3 MR. JAMES: Object to the nonresponsive 4 answer. 5 THE WITNESS: Maybe you can clarify 6 your question, because I'm -- maybe I didn't 7 understand what you were asking. 8 BY MR. JAMES: 9 Q. Sure. Dr. Moorman, you provided these 10 examples in your report; correct? 11 A. These are examples to make the point that, as 12 we have said here, that some people weigh different 13 parts of the evidence a bit differently. 14 Q. And so if someone who's reading your report 15 gets an impression that you are equating the body of 16 scientific and medical evidence on the issue of 17 smoking and lung cancer to the body of scientific 18 evidence on talc and ovarian cancer, then they would 19 be getting the wrong impression; is that correct? 20 MS. PARFITT: Objection. 21 THE WITNESS: I don't think that I am 22 equating the evidence for the two. I am -- equating 23 the evidence for the two types of cancer. I was using 24 that to illustrate -- to support the sentence right 25 before that, is that, when we look at these Hill</p>
<p style="text-align: right;">Page 143</p> <p>1 of evidence we have in 2019 as to talc and ovarian 2 cancer? 3 A. To say that it is the same is -- I don't know 4 that you can say that it's the same. It's different 5 studies done in different time frames. The assessment 6 of the exposure is a bit different. 7 So there are similarities and, you know, the 8 criteria that I applied to come to my conclusion of 9 causality, I think, are similar to what has been 10 applied to smoking and lung cancer. But the data are 11 different. There are different studies, different 12 time frame. 13 Q. Would you say that the data on smoking and 14 lung cancer is stronger than the data on talc and 15 ovarian cancer -- 16 MS. PARFITT: Objection. 17 BY MR. JAMES: 18 Q. -- to support a causal conclusion? 19 A. I'm not sure why one would make such a 20 comparison of what is stronger or not. I mean, 21 clearly, we know that smoking and lung cancer is one 22 of the strongest associations between an exposure and 23 a cancer. 24 The odds ratio that is associated with talc 25 use and ovarian cancer is not as large, but I think</p>	<p style="text-align: right;">Page 145</p> <p>1 factors, scientists can look at them and they might 2 weight one more heavily than another. 3 BY MR. JAMES: 4 Q. And you -- you believe that the medical 5 community accepts that smoking is a cause of lung 6 cancer; correct? 7 A. Yes, in general, I think that's true. 8 Q. Does the medical community believe that talc 9 is a cause of ovarian cancer? Is that the medical 10 community's consensus? 11 MS. PARFITT: Objection. Form. 12 THE WITNESS: I'm not sure who you mean 13 by "the medical community." I -- I think that there 14 are certainly -- there's plenty of evidence to support 15 my conclusion. We have evidence very recently from 16 Health Canada that they have come to the same 17 conclusion. So... 18 BY MR. JAMES: 19 Q. Did Health Canada come to a causal 20 conclusion? 21 A. That was my reading of their document. 22 Q. When's the last time you've read the 23 documents from Health Canada? 24 A. Probably within the last few days. 25 Q. Did Plaintiffs' counsel provide those to you?</p>

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<p>1 A. Yes, they did.</p> <p>2 Q. Okay. And your recollection is that the</p> <p>3 Health Canada documents state that talc is a cause of</p> <p>4 ovarian cancer?</p> <p>5 A. I definitely recall them using the "causal"</p> <p>6 language in the document. If -- we can pull it up if</p> <p>7 we want to confirm the precise language.</p> <p>8 Q. Other than identifying Health Canada, which</p> <p>9 you've just done, are there any other bodies or</p> <p>10 scientific organizations or medical organizations that</p> <p>11 you can cite to that have concluded that talc is a</p> <p>12 cause of ovarian cancer?</p> <p>13 A. We've already discussed the IARC conclusion</p> <p>14 that it's possibly carcinogenic.</p> <p>15 Q. And so, again, I'm asking you about -- sorry.</p> <p>16 A. Sorry. Go ahead.</p> <p>17 Q. Sorry. My apologies.</p> <p>18 A. Okay.</p> <p>19 Q. Were you done?</p> <p>20 A. I'm finished.</p> <p>21 Q. So my question, I think, is different than</p> <p>22 that the one you're answering.</p> <p>23 A. Yeah.</p> <p>24 Q. So I'm asking you if you're aware of any</p> <p>25 scientific or medical bodies that have concluded that</p>	<p>1 ovarian cancer. So...</p> <p>2 Q. And when you say talc -- sorry. I think</p> <p>3 you're dropping off a bit, and so I'm jumping in too</p> <p>4 quickly. And I apologize.</p> <p>5 Are you done?</p> <p>6 A. I'm finished, yes.</p> <p>7 Q. You're referring there to a journal article;</p> <p>8 is that right?</p> <p>9 A. It was a summary of -- I think it was</p> <p>10 something like "What's new in ovarian cancer." It was</p> <p>11 published maybe --</p> <p>12 Q. And do you believe the article that you're</p> <p>13 referring to represents the consensus view of the</p> <p>14 medical community?</p> <p>15 MS. PARFITT: Objection. Form.</p> <p>16 THE WITNESS: I don't know that it does</p> <p>17 or not. It wasn't presented as the official opinion</p> <p>18 of that organization.</p> <p>19 BY MR. JAMES:</p> <p>20 Q. And the article that you were mentioning, you</p> <p>21 said increased risk -- or increased association. Is</p> <p>22 that what you said? I don't have the realtime in</p> <p>23 front of me right now.</p> <p>24 A. I don't have it in front of me either.</p> <p>25 Q. Okay.</p>
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<p>1 talc is a general cause of ovarian cancer.</p> <p>2 A. I'm not aware of a -- I'm not aware of a</p> <p>3 statement that has been published, other than the ones</p> <p>4 that I mentioned.</p> <p>5 Q. And by others that you mentioned, you're</p> <p>6 referring to the Health Canada document?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And we will turn back to that, and</p> <p>9 that way we can have a copy in front of us both.</p> <p>10 Okay?</p> <p>11 A. Okay.</p> <p>12 Q. With regard to IARC, again, you understand</p> <p>13 that they have concluded "possible." Correct?</p> <p>14 A. They conclude possible at that point in time,</p> <p>15 which was 2010.</p> <p>16 Q. Have you ever looked to see if any medical</p> <p>17 organizations that represent the gynecologic oncology</p> <p>18 community have concluded that talc is a cause of</p> <p>19 ovarian cancer?</p> <p>20 A. I am aware that, in a recent article in</p> <p>21 Obstetrics and Gynecology, which is one of the leading</p> <p>22 journals in the field, they were summarizing some of</p> <p>23 the information that is new. They were describing the</p> <p>24 Penninkilampi meta-analysis, and their conclusion was</p> <p>25 that talc is associated with increased risk for</p>	<p>1 A. I am recalling something like there is --</p> <p>2 I don't know what the phrasing was. It's associated</p> <p>3 with increased risk or there is an increased risk of</p> <p>4 ovarian cancer with talc use.</p> <p>5 Q. Do you recall if that article made a</p> <p>6 statement on causality?</p> <p>7 A. I don't recall.</p> <p>8 Q. Have you consulted information provided by</p> <p>9 the ACOG or the SGO with respect to the talc ovarian</p> <p>10 cancer hypothesis?</p> <p>11 MS. PARFITT: Objection.</p> <p>12 THE WITNESS: I don't recall if I have</p> <p>13 or not.</p> <p>14 BY MR. JAMES:</p> <p>15 Q. Would you be interested to know the positions</p> <p>16 by the leading organizations for the gynecologic</p> <p>17 oncology community on this issue?</p> <p>18 MS. PARFITT: Objection. Form.</p> <p>19 THE WITNESS: Of course. Any</p> <p>20 information is important to know.</p> <p>21 MR. JAMES: I'm going to mark as</p> <p>22 Exhibit No. 18 a copy of a statement issued by ACOG on</p> <p>23 talc use and ovarian cancer.</p> <p>24 (Exhibit No. 18 was marked for identification.)</p> <p>25 MR. JAMES: I'm handing you two copies</p>

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<p>1 again.</p> <p>2 BY MR. JAMES:</p> <p>3 Q. Dr. Moorman, have you seen this statement</p> <p>4 before?</p> <p>5 A. I don't recall if I have or not. I might</p> <p>6 have.</p> <p>7 Q. Do you see at the bottom of the statement --</p> <p>8 it's a single paragraph -- the statement concludes</p> <p>9 with the quote (as read):</p> <p>10 "There was no medical consensus</p> <p>11 that talcum powder causes ovarian</p> <p>12 cancer."</p> <p>13 Do you see where I was reading?</p> <p>14 A. I do see that.</p> <p>15 Q. Do you disagree with that statement?</p> <p>16 A. Again, going back to the recent conclusion</p> <p>17 from Health Canada, I think that that is some evidence</p> <p>18 of medical consensus. And I do acknowledge that</p> <p>19 this -- what is said here, that -- yeah, I acknowledge</p> <p>20 what they have written here, yes.</p> <p>21 Q. Have you, in preparing your report for this</p> <p>22 litigation, have you taken a look to see what the</p> <p>23 National Cancer Institute has said about the purported</p> <p>24 association between talc and ovarian cancer?</p> <p>25 A. Yes, I have.</p>	<p>1 inadequate evidence of an association?</p> <p>2 A. Yes.</p> <p>3 And if I may address this document --</p> <p>4 Q. If you could give me just one second, and</p> <p>5 then --</p> <p>6 A. Okay.</p> <p>7 Q. -- I'll let you finish, if you don't mind.</p> <p>8 A. Okay.</p> <p>9 Q. Have you considered this before?</p> <p>10 A. Have I --</p> <p>11 MS. PARFITT: Objection.</p> <p>12 BY MR. JAMES:</p> <p>13 Q. Yes.</p> <p>14 A. -- considered it?</p> <p>15 Q. In forming your opinions in this case?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. It's not cited or discussed in your</p> <p>18 report, is it?</p> <p>19 A. I don't know that I have, but again, it's one</p> <p>20 of the documents that I have -- I have seen in my --</p> <p>21 in my work.</p> <p>22 Q. And so within your report, you do discuss</p> <p>23 findings of IARC; correct?</p> <p>24 A. Yes.</p> <p>25 Q. But you don't discuss findings of the NCI; is</p>
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<p>1 Q. Okay. And what do they say?</p> <p>2 A. I -- when you are -- I think you are</p> <p>3 referring to the PDQ --</p> <p>4 Q. Yes.</p> <p>5 A. -- from NCI.</p> <p>6 Q. Would you like a copy of it?</p> <p>7 A. I would very much like a copy.</p> <p>8 Q. Fair enough.</p> <p>9 Okay. Dr. Moorman, I'm going to hand you a</p> <p>10 copy of the NCI PDQ on "Ovarian, Fallopian Tube, and</p> <p>11 Primary Peritoneal Cancer, Health Professional</p> <p>12 Version."</p> <p>13 (Exhibit No. 19 was marked for identification.)</p> <p>14 THE WITNESS: Thank you.</p> <p>15 BY MR. JAMES:</p> <p>16 Q. And if you turn to -- this is not paginated,</p> <p>17 unfortunately -- have you gotten there already? Or</p> <p>18 I can count for us. I flipped seven times to get</p> <p>19 there. Looks like you beat me to it.</p> <p>20 A. Okay.</p> <p>21 Q. And do you see here that is this the PDQ you</p> <p>22 were thinking of, Dr. Moorman?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And in here, do you see that the NCI</p> <p>25 has listed perineal talc exposure as a factor with</p>	<p>1 that right?</p> <p>2 A. I don't think that I specifically addressed</p> <p>3 it.</p> <p>4 Q. Is that because it conflicts with your</p> <p>5 litigation opinion?</p> <p>6 MS. PARFITT: Objection.</p> <p>7 THE WITNESS: No.</p> <p>8 May I ask --</p> <p>9 BY MR. JAMES:</p> <p>10 Q. And, Dr. Moorman, you said you wanted to</p> <p>11 comment, and now is fine.</p> <p>12 A. Let's see. I wanted -- when did you print</p> <p>13 out this version of the PDQ, if I may ask you?</p> <p>14 Q. So do you understand that this is a -- this</p> <p>15 is a -- well, if you turn to the back page of the copy</p> <p>16 that I handed you --</p> <p>17 A. Mm-hmm.</p> <p>18 Q. -- the very back --</p> <p>19 A. Okay.</p> <p>20 Q. -- it says "Updated: December 21, 2018."</p> <p>21 A. Okay.</p> <p>22 Q. All the way on the back page.</p> <p>23 A. Yeah.</p> <p>24 Q. Got it.</p> <p>25 A. Okay. One of the -- I have looked at this</p>

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<p>1 very recently, and on the online version, there were 2 some rather what I considered kind of interesting 3 conclusions that were made. I'm actually not seeing 4 it in this version here. But, for example, they -- 5 I'm sorry. I don't see it even mentioned here. 6 But on the online version, they had listed 7 DMPA -- depot medroxyprogesterone acetate -- as 8 something that there was adequate evidence of reduced 9 effect. And they were basing that -- there are very 10 few studies on that to begin with, and as they 11 summarized it, again, the last time I looked at it 12 online, they said it was inconsistent data, but they 13 still summarized that there was adequate evidence. 14 And then in regard to things like comparing 15 the evidence for something like breastfeeding, they 16 said (as read): 17 "Based on solid evidence, 18 breastfeeding is associated with 19 decreased risk of ovarian cancer." 20 If we compare the evidence to breastfeeding 21 to the evidence for talcum -- talc use, again, the 22 online version that I last looked at, it gave a little 23 bit more detail about the meta-analyses and so on. 24 So the meta-analyses for breastfeeding and 25 the meta-analyses for talc, there were a lot of</p>	<p>1 with the NCI? 2 A. Okay. Just looking at this, and it came 3 up -- it says "with inadequate evidence of an 4 association." 5 Did you say "adequate" or "inadequate"? 6 Q. I said "inadequate." 7 A. Okay. My judgment based on the evidence is 8 that there is adequate evidence. So I would disagree 9 with the NCI in the conclusion that they reached. 10 Q. With regard to your discussion that we've had 11 just now on the body of evidence to look at 12 breastfeeding and ovarian cancer risk -- 13 A. Yes. 14 Q. -- and this is a yes-or-no question -- did 15 you conduct a comprehensive review of the scientific 16 medical literature and evidence surrounding the 17 association between breastfeeding and ovarian cancer? 18 A. I did not do as comprehensive a review of 19 that literature as I did for the talc. 20 Q. And have you, in the course of your career, 21 ever looked comprehensively at the body of scientific 22 and medical evidence surrounding the association of 23 breastfeeding and ovarian cancer to the cell studies, 24 the plausibility, the dose-response, have you done all 25 of that with respect to breastfeeding and ovarian</p>
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<p>1 similarities. There are roughly 30 studies addressing 2 each of them. For breastfeeding, it's about a 3 25 percent reduction in risk; for talc, about a 4 25 percent increased risk. 5 When you look at the overall number of 6 studies, roughly 90 percent of them support 7 breastfeeding -- in terms of just looking at the 8 direction of the effect -- about 90 percent of them 9 support that breastfeeding is associated with reduced 10 risk. When you look at the meta-analyses for talc, 11 about 90 percent of the studies have an odds ratio 12 greater than 1. 13 And so when we look at the overall body of 14 evidence, to me, I think it's comparable for 15 breastfeeding versus talc, but they conclude that the 16 evidence is adequate for breastfeeding but not 17 adequate for talc. And they don't really describe 18 their methodology for how they reach their 19 conclusions. 20 So it leaves me just a little bit baffled 21 about why is one adequate evidence and one inadequate 22 evidence. 23 Q. If the NCI's PDQ that's available on their 24 website as of today classifies talc as a factor with 25 inadequate evidence of an association, do you disagree</p>	<p>1 cancer? 2 A. I -- in the course of looking at ovarian 3 cancer, I have actually never written a paper that was 4 strictly focused on breastfeeding and ovarian cancer, 5 and that is typically where one would go through the 6 very comprehensive review. 7 I am familiar with much of the literature, 8 but the degree to which I reviewed the literature was 9 not in the same level of detail as I did the talc 10 literature. 11 Q. And do you know if the scientists at the NCI 12 who have commented on the association between 13 breastfeeding and ovarian cancer have conducted an 14 examination of the scientific and medical literature 15 that is more comprehensive, less comprehensive, or the 16 same that you've conducted? 17 MS. PARFITT: Objection to form. 18 THE WITNESS: They do not describe 19 their methodology, and so I can't say if it was more 20 or less comprehensive. 21 BY MR. JAMES: 22 Q. Okay. Dr. Moorman, on page 10 of your 23 report -- 24 A. Yes. 25 Q. -- you have the -- it's the third full</p>

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<p>1 paragraph down, and you make the statement that</p> <p>2 meta-analyses are "considered to be some of the</p> <p>3 strongest evidence for a causal association."</p> <p>4 Do you see where I'm reading that?</p> <p>5 A. Yes, I do.</p> <p>6 Q. Okay. So that's -- so you've made that</p> <p>7 comment.</p> <p>8 And then further down, you say (as read):</p> <p>9 "Data from meta-analyses are</p> <p>10 particularly important for</p> <p>11 evaluating exposure-disease</p> <p>12 relationships such as talc and</p> <p>13 ovarian cancer where the relative</p> <p>14 risks for most individuals are</p> <p>15 approximately 1.2 to 1.5."</p> <p>16 Do you see where I've read that?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Can you cite any published authority for the</p> <p>19 statement that meta-analyses are considered to be some</p> <p>20 of the strongest evidence for causal association?</p> <p>21 A. I'm trying to think of whether it's a</p> <p>22 published source. It's something that I have seen,</p> <p>23 for example, multiple times in lectures and so on</p> <p>24 where it will give a hierarchy of evidence. And</p> <p>25 meta-analyses combining data from multiple studies is</p>	<p>1 data as reported. It could not correct the bias.</p> <p>2 Q. So to the extent the meta-analyses are</p> <p>3 collecting data from underlying studies that are</p> <p>4 flawed by recall bias or confounding, those</p> <p>5 inaccuracies carry over into the meta-analyses;</p> <p>6 correct?</p> <p>7 MS. PARFITT: Objection.</p> <p>8 THE WITNESS: I would not characterize</p> <p>9 it as "carry over." We recognize when we combine the</p> <p>10 data from the meta-analyses, it is combining the</p> <p>11 reported data. If there were biases that either led</p> <p>12 to an underestimate or an overestimate of the relative</p> <p>13 risk, they are not correcting that.</p> <p>14 BY MR. JAMES:</p> <p>15 Q. And do you caution the reader of your MDL</p> <p>16 report about that limitation to meta-analyses anywhere</p> <p>17 in your report?</p> <p>18 A. I do not specifically make that caution, no.</p> <p>19 Q. The meta-analyses that we have on the talc</p> <p>20 ovarian cancer issue, they are progressed over a</p> <p>21 period of time; correct?</p> <p>22 A. That is correct.</p> <p>23 Q. And we know that there's been two recent</p> <p>24 meta-analyses. And all of the meta-analyses that have</p> <p>25 been published on this association are in some ways</p>
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<p>1 often put at kind of the top of the pyramid for making</p> <p>2 causal assessments.</p> <p>3 I want to say that maybe some of the</p> <p>4 evidence-based medicine -- I know that there are</p> <p>5 online summaries of evidence-based medicine that would</p> <p>6 describe meta-analyses as kind of some of the</p> <p>7 strongest evidence for causality.</p> <p>8 Q. Meta-analyses combine data from underlying</p> <p>9 studies; correct?</p> <p>10 A. That is correct.</p> <p>11 Q. Meta-analyses do not correct for bias and</p> <p>12 confounding in underlying studies; correct?</p> <p>13 A. The meta-analysis itself -- no. They combine</p> <p>14 the data. They...</p> <p>15 Q. And -- were you finished?</p> <p>16 A. Yeah. They do not correct for the bias.</p> <p>17 Q. Meta-analyses, for example, do not eliminate</p> <p>18 recall bias if there is a recall bias problem in the</p> <p>19 underlying studies; correct?</p> <p>20 A. That is correct. Meta-analyses cannot do</p> <p>21 that.</p> <p>22 Q. And the meta-analyses studies that you</p> <p>23 reviewed and discussed in your report all concede that</p> <p>24 point, don't they?</p> <p>25 A. They acknowledge that they are combining the</p>	<p>1 overlapping; correct?</p> <p>2 MS. PARFITT: Objection to form.</p> <p>3 THE WITNESS: The meta-analyses, their</p> <p>4 intent is to combine all the published data. So, yes,</p> <p>5 there is some overlap. More recent ones would have</p> <p>6 included studies that had been published in prior</p> <p>7 meta-analyses.</p> <p>8 BY MR. JAMES:</p> <p>9 Q. And recognizing that meta-analyses can differ</p> <p>10 here and there for various -- various reasons, the</p> <p>11 talc ovarian cancer meta-analyses generally pull data</p> <p>12 from the same body of literature; is that fair?</p> <p>13 A. Yes.</p> <p>14 Q. And any suggestion that because you have</p> <p>15 multiple meta-analyses reaching around the same odds</p> <p>16 ratio and that that somehow demonstrates consistency,</p> <p>17 isn't that a little bit misleading?</p> <p>18 MS. PARFITT: Objection. Form.</p> <p>19 THE WITNESS: I think that when we look</p> <p>20 at it, when we see that, early on, you see some</p> <p>21 meta-analyses were done, I want to say maybe in the</p> <p>22 '90s, and then as more data are added in, you -- they</p> <p>23 still settled in on roughly the same summary odds</p> <p>24 ratio as even more data were accumulated.</p> <p>25 Sometimes there is a concern that early on</p>

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<p>1 the studies with positive associations are published, 2 and then after -- as time goes on, other studies are 3 done that didn't find that association. So you would 4 expect that the summary odds ratio might become 5 attenuated as more studies were added. 6 And that's not the situation with the talc 7 literature. It's been pretty consistent from the 8 meta-analyses done in the 1990s to the 2000s to 2018. 9 BY MR. JAMES: 10 Q. And the 2018 meta-analyses that they are 11 grabbing in the studies from decades prior, they're 12 grabbing in the same studies that the 1990s 13 meta-analyses grabbed in; right? 14 MS. PARFITT: Objection. Form. 15 THE WITNESS: Yeah. The purpose is to 16 include all of the published data. So yes, of course. 17 BY MR. JAMES: 18 Q. And in your report, you place significant 19 emphasis -- if that's a fair word -- on meta-analyses. 20 Is that a fair way to describe it? 21 MS. PARFITT: Objection. 22 THE WITNESS: Yes, I think I -- I think 23 that's fair to characterize it that way. 24 BY MR. JAMES: 25 Q. You -- did you read the conclusions of all of</p>	<p>1 opportunity to ask questions afterwards. 2 A. Some of them did raise some concerns about 3 whether or not it could be a causal association. 4 Q. We're going to take a look at the studies 5 shortly as I grab these folders out. 6 Did you report in your report for the MDL 7 any of the cautionary language from these 8 meta-analyses about causation? 9 A. I -- in my report, when you look at some of 10 the cautionary language, they will refer to perhaps 11 concerns about recall bias or things like that. 12 In my report, I went through potential 13 biases and how I weighed that and whether I thought it 14 was an important concern in the studies that 15 contributed to the meta-analyses. 16 Q. Did you talk about any weaknesses or problems 17 with the meta-analyses themselves? 18 A. I don't believe I did in my report. 19 Q. And just -- okay. 20 MR. JAMES: I'm going to mark as 21 Exhibit No. 20 a meta-analysis that I think that 22 you've mentioned this morning. It's the Penninkilampi 23 study. 24 THE WITNESS: Yes. 25 MR. JAMES: I'm going to hand you two</p>
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<p>1 the meta-analyses performed to date? 2 A. I did. 3 Q. Do any of the authors of the meta-analyses 4 performed to date conclude causation? 5 A. If I may take a minute to address the issue 6 of how causation is reported in the epidemiologic 7 literature. 8 Q. With all due respect, Doctor, if you could 9 just answer the question. 10 A. I think that they typically refer to, like, 11 increased risk. I don't know that any of them refer 12 to -- made the conclusion of -- I don't know that they 13 used the word "causal." 14 Q. In fact, many of the meta-analyses 15 specifically caution against a causal interpretation, 16 don't they? 17 MS. PARFITT: Objection. 18 THE WITNESS: Once again, if -- may 19 I take a moment to address how the word -- 20 BY MR. JAMES: 21 Q. Because my time is limited -- 22 A. Okay. 23 Q. -- I'm really going to have to respectfully 24 ask you to answer my question to the extent that 25 you're able, and then your counsel will have an</p>	<p>1 copies again. 2 (Exhibit No. 20 was marked for identification.) 3 MR. JAMES: It's marked as Exhibit 20. 4 THE WITNESS: Would this be a good time 5 to take a break before we get into -- 6 MR. JAMES: Absolutely. 7 THE WITNESS: Okay. 8 THE VIDEOGRAPHER: Going off record at 9 1:48 p.m. 10 (Recess taken from 1:48 p.m. to 2:03 p.m.) 11 THE VIDEOGRAPHER: Back on record at 12 2:03 p.m. 13 BY MR. JAMES: 14 Q. Dr. Moorman, I handed you had a copy of the 15 Penninkilampi paper. 16 A. I'm sorry, the papers were moved while 17 I was... 18 Q. It was marked as Exhibit 20, I believe. 19 Here, I have an extra, if that would speed 20 things along. I'm sure it's somewhere in there. 21 A. It got moved around. Oh, here it is. 22 Q. Okay. Again, Dr. Moorman, this is one of the 23 meta-analyses that you reviewed to inform your 24 opinions in this case; correct? 25 A. That is correct.</p>

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<p style="text-align: right;">Page 166</p> <p>1 Q. It's also one of the more recent 2 meta-analyses on the issue; correct? 3 A. That's correct. 4 Q. And what did the Penninkilampi authors say 5 about causation? 6 A. Okay. They describe perineal talc is 7 associated with a 24 to 39 percent increased risk of 8 ovarian cancer. 9 And this is a very typical way that it would 10 be described in the epidemiologic literature. It -- 11 as described very eloquently in some articles in the 12 American Journal of Public Health last spring, they 13 noted that, to the detriment of the science, that 14 epidemiologists are frequently loathe -- or don't 15 often use the word "causal" when they describe a risk 16 factor; and, in part, this is because we are relying 17 on observational data. This is not an experimental 18 study. 19 And so, many times, reviewers, if they refer 20 to "we found that talc caused ovarian cancer," they 21 would object to that, saying that it wasn't a 22 randomized controlled trial. 23 But in this series of articles in the 24 American Journal of Public Health, they indicated that 25 the tendency not to use the word "causal" is to the</p>	<p style="text-align: right;">Page 168</p> <p>1 "Hence, while perineal talc use 2 has not been shown to be safe, in 3 a similar regard, a certain causal 4 link between talc use and ovarian 5 cancer has not yet been 6 established." 7 That's what the authors say; correct? 8 A. That's what they say, yes. 9 Q. Okay. So they caution that causation has not 10 been established; correct? 11 MS. PARFITT: Objection. 12 THE WITNESS: They say a certain causal 13 link has not been established -- not yet been 14 established. 15 BY MR. JAMES: 16 Q. And you're here today testifying about what 17 you believe to be evidence supporting the causal link; 18 correct? 19 A. Yes, I am -- I am. 20 Q. Okay. And so where in your report do you 21 advise the reader that the Penninkilampi authors 22 expressed reservations about causation? 23 A. I do not have anything like that in my 24 report. 25 MR. JAMES: The next meta-analysis that</p>
<p style="text-align: right;">Page 167</p> <p>1 detriment of the science. It's like "Why would we be 2 looking at risk factors for a disease if we didn't 3 think that it caused the disease?" 4 So I think that when an epidemiologist sees 5 an increased risk of ovarian cancer, we are thinking 6 that this is -- this causes ovarian cancer. 7 Q. But epidemiologists, including many of the 8 meta-analyses that we're about to review, have talked 9 about cause, haven't they? 10 MS. PARFITT: Objection. 11 THE WITNESS: Some of them have 12 addressed, yes. 13 BY MR. JAMES: 14 Q. For example, Penninkilampi doesn't seem shy 15 of the word "cause." If we look at page 42, 16 Dr. Moorman, we see, in the top paragraph in the 17 left-hand column, at the bottom of that paragraph, the 18 Penninkilampi authors write, quote -- this is the last 19 sentence -- 20 A. Wait. Page 42? 21 Q. Page 42. 22 A. Yes. 23 Q. It's the top left paragraph. The bottom last 24 sentence of that paragraph, the authors state 25 (as read):</p>	<p style="text-align: right;">Page 169</p> <p>1 we can look at is the Berg -- or Berge meta-analysis. 2 I'm going to mark that as Exhibit 21. 3 (Exhibit No. 21 was marked for identification.) 4 BY MR. JAMES: 5 Q. Do the Berge authors conclude that the 6 evidence is sufficient to support a causation 7 conclusion? 8 A. They do not make that conclusion, no. 9 Q. In fact, they actually -- they do address 10 causation, don't they? 11 A. They state their opinion, yes. 12 Q. Okay. And their opinion is expressed several 13 times throughout the article. The first is in the 14 abstract of the article; correct? 15 If we look at the abstract, it's the first 16 page of the article, page 248, the last sentence of 17 the abstract. Do you see that? 18 A. Yes, I do. 19 Q. They say (as read): 20 "The heterogeneity of results by 21 study design, however, detracts 22 from a causal interpretation of 23 this association." 24 Correct? 25 A. That's what it says, yes.</p>

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<p>1 Q. Where do you advise the reader of your MDL 2 report that the authors of the Berge meta-analyses 3 expressed reservations about causation? 4 MS. PARFITT: Objection. Form. 5 THE WITNESS: That is not in my report. 6 BY MR. JAMES: 7 Q. Do you see at the very the end of article, at 8 the very last page on 256, before the acknowledgment 9 section, again, the authors conclude the article with 10 a statement that the results (as read): 11 "do not support a causal 12 interpretation of the 13 association." 14 Do you see where I'm reading? 15 A. They say some -- several aspects of the 16 results there. 17 Q. Fair enough. 18 A. Yes. 19 Q. So let's just read the sentence in full. So 20 they say (as read): 21 "Several aspects of our results, 22 including the heterogeneity of 23 results between case-control and 24 cohort studies, however, do not 25 support a causal interpretation of</p>	<p>1 MR. JAMES: And I'm going to reserve 2 the time that it takes -- 3 MS. PARFITT: No, you're not going to 4 reserve the time. You asked her a question; she was 5 answering it. 6 MR. JAMES: It was a yes-or-no 7 question. 8 MS. PARFITT: You can object -- it was 9 not, Scott. Let's have her finish her statement, and 10 you can decide what you want to do it with it. But 11 she's going to finish her comment. 12 Dr. Moorman, please. 13 THE WITNESS: So I think that in my 14 report, I did address the aspects of the heterogeneity 15 of the results, although I might not specifically have 16 addressed -- said anything specifically about the 17 limitation of the Berge. 18 BY MS. PARFITT: 19 Q. Right. So my question, which was very 20 precise, is where do you note in your MDL report the 21 causation reservations of the Berge authors? 22 MS. PARFITT: Objection. 23 THE WITNESS: And as I stated before, 24 that is not in -- that specific reservations of the 25 Berge authors, I do not have that in my -- in my</p>
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<p>1 the association." 2 That's what they say; correct? 3 A. Right. 4 Q. And, again, do you advise the readers of your 5 MDL report that those are the conclusions of the Berge 6 meta-analysis? 7 MS. PARFITT: Objection. Form. 8 THE WITNESS: I do not specifically do 9 that. But in my report, I think that I really address 10 some of the heterogeneity of the results between 11 case-control and cohort studies and why some of the 12 differences might be observed and, for example, some 13 of the biases in the cohort studies would lead to an 14 underestimate of the -- 15 BY MR. JAMES: 16 Q. And, Dr. Moorman -- 17 MS. PARFITT: Excuse me -- 18 BY MR. JAMES: 19 Q. -- I'm going to ask you questions about that. 20 MS. PARFITT: -- Mr. James, she was in 21 the middle of her sentence. 22 MR. JAMES: I object to the 23 nonresponsive portion of her answer. 24 MS. PARFITT: You may, but let her 25 complete her answer.</p>	<p>1 report. 2 BY MS. PARFITT: 3 Q. The next meta-analyses is -- and I'm working 4 backwards chronologically -- is the Langseth 5 meta-analyses. 6 Are you familiar with that paper? 7 A. Yes, I have seen that paper. 8 MR. JAMES: And I'm going to mark the 9 Langseth paper as Exhibit No. 23. 10 (Exhibit No. 22 was marked for identification.) 11 MR. JAMES: I'm handing you two copies. 12 MR. DONATH: 23 or 22? 13 MS. BRENNAN: 22. 14 MR. JAMES: It's 22. So we'll sub 15 stickers. 16 BY MR. JAMES: 17 Q. So Langseth is 22. Did the authors of 18 Langseth conclude that causation is shown? Yes or no, 19 please. 20 A. They -- if I may take just a moment to read 21 through it -- 22 Q. Sure. 23 A. -- as it... 24 No, they do not. 25 Q. And, in fact, the authors do address the</p>

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<p style="text-align: right;">Page 174</p> <p>1 issue of causation on page 359 of the article; 2 correct, under the section "Proposal to research 3 community." 4 Do you see where I am? 5 A. I do see that. 6 Q. Okay. And the authors state (as read): 7 "The current body of experimental 8 and epidemiological evidence is 9 insufficient to establish a causal 10 association between perineal use 11 of talc and ovarian cancer risk." 12 A. That is correct. And, again, noting the date 13 of this paper, 2008. So quite a lot of evidence has 14 emerged since then. And one of the authors on the 15 paper has since concluded that there is sufficient 16 evidence for causality. 17 Q. And you're talking about a paid expert in 18 this case; correct? 19 MS. PARFITT: Objection. 20 THE WITNESS: Dr. Siemiatycki, who's a 21 paid expert, well-respected epidemiologist. 22 BY MR. JAMES: 23 Q. And he's a paid expert in this litigation for 24 the Plaintiffs; correct? 25 MS. PARFITT: Objection.</p>	<p style="text-align: right;">Page 176</p> <p>1 conclude that the evidence was sufficient to support 2 causation? 3 A. No, they did not. 4 Q. Okay. And, in fact, the authors did address 5 causation in their paper in the abstract; correct? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: Yes, they do. 8 BY MR. JAMES: 9 Q. Okay. And at page 195 in the conclusion of 10 the abstract, the authors say (as read): 11 "The available observational data 12 do not support the existence of a 13 causal relationship between 14 perineal talc exposure and 15 increased risk of epithelial 16 ovarian cancer. Selection bias 17 and uncontrolled confounding may 18 account for the positive 19 associations seen in prior 20 epidemiological studies." 21 That's what the authors say; correct? 22 A. That is what these authors say. 23 Q. And did you report to the reader of your MDL 24 report the Huncharek authors' reserved judgment on 25 causation?</p>
<p style="text-align: right;">Page 175</p> <p>1 THE WITNESS: That is correct. 2 BY MR. JAMES: 3 Q. Where in your report -- and this is a 4 yes-or-no question, or actually it's not "yes" or 5 "no." You tell me if it exists or not. 6 Where in your report do you show to the 7 reader of the report that the Langseth authors 8 reserved judgment on causation? 9 MS. PARFITT: Objection to form. 10 THE WITNESS: I did not specifically 11 include that in my report. 12 BY MR. JAMES: 13 Q. Dr. Moorman, have you reviewed the Huncharek 14 2003 meta-analyses? 15 A. Yes, I have. 16 MR. JAMES: And I'm going to mark the 17 Huncharek 2003 meta-analyses as Exhibit No. 23, and 18 we'll switch stickers at the break. 19 (Exhibit No. 23 was marked for identification.) 20 BY MR. JAMES: 21 Q. I'm handing you two copies, Dr. Moorman. 22 Is this another meta-analysis that you 23 reviewed in forming your opinions in this case? 24 A. Yes, it is. 25 Q. Okay. Did the authors of this meta-analysis</p>	<p style="text-align: right;">Page 177</p> <p>1 MS. PARFITT: Objection. 2 THE WITNESS: As with the other 3 meta-analysis, this is now 16 years old, and I did not 4 specifically report that, but I did consider in my 5 report the biases and uncontrolled confounding that 6 they were concerned about. 7 BY MR. JAMES: 8 Q. Do any of the -- there are a handful of 9 meta-analyses that precede the Huncharek 2003 10 meta-analyses; correct? 11 A. That is correct. 12 Q. Do any of those meta-analyses conclude 13 causation? 14 MS. PARFITT: Objection. Form. 15 THE WITNESS: I don't believe that they 16 do. 17 BY MR. JAMES: 18 Q. And returning back to our discussion on the 19 Langseth meta-analyses, you noted sort of -- when I 20 asked you a question about their conclusions on 21 causation, you noted the timing of the article; 22 correct? 23 A. Yes. 24 Q. You noted that the article was published 25 in --</p>

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<p>1 A. 2008.</p> <p>2 Q. -- 2008?</p> <p>3 A. Yes.</p> <p>4 Q. That is right?</p> <p>5 So is your opinion that the evidence in 2008</p> <p>6 was, in fact, insufficient to support a causal</p> <p>7 conclusion but has now transitioned to a status where</p> <p>8 it is sufficient?</p> <p>9 MS. PARFITT: Objection. Form.</p> <p>10 THE WITNESS: You have asked me that</p> <p>11 question in -- that or a similar question before.</p> <p>12 There is a growing body of evidence.</p> <p>13 I would be hard-pressed to say at what point in time,</p> <p>14 you know, it reached the tipping point where there is</p> <p>15 enough evidence to say that there is this causal</p> <p>16 association.</p> <p>17 At this point in time, I feel very confident</p> <p>18 in saying that, but I can't say when sufficient data</p> <p>19 accumulated to say that. I think that's an impossible</p> <p>20 answer -- or an impossible question to answer.</p> <p>21 BY MR. JAMES:</p> <p>22 Q. And the reason I asked it again is because</p> <p>23 you made the qualification in discussing the Langseth</p> <p>24 paper. When I asked you about the authors'</p> <p>25 conclusions on causation, you specifically noted that</p>	<p>1 A. No --</p> <p>2 MS. PARFITT: Objection.</p> <p>3 THE WITNESS: -- for the same reasons</p> <p>4 I described prior.</p> <p>5 MR. JAMES: And I'm going to mark the</p> <p>6 2013 Terry paper as Exhibit 24.</p> <p>7 (Exhibit No. 24 was marked for identification.)</p> <p>8 MR. JAMES: I think I'm back on track</p> <p>9 on the numbers. I'm handing you two copies.</p> <p>10 BY MR. JAMES:</p> <p>11 Q. And again, Dr. Moorman, you've used this</p> <p>12 paper to inform your opinions in the case; correct?</p> <p>13 A. That is correct.</p> <p>14 Q. And if you look at the last page of the text</p> <p>15 on 820 with me, you see in the last paragraph, which</p> <p>16 is -- the last paragraph on page 820, the authors</p> <p>17 state at the top right-hand column (as read):</p> <p>18 "More work is needed to understand</p> <p>19 how genital powders may exert a</p> <p>20 carcinogenic effect and which</p> <p>21 constituents may be involved."</p> <p>22 Do you see that sentence?</p> <p>23 A. Yes, I do.</p> <p>24 Q. There, the authors are again noting that --</p> <p>25 let me rephrase it this way.</p>
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<p>1 it was a paper from the 2008 time frame; correct?</p> <p>2 A. Right. And I think that -- I think that it</p> <p>3 is obvious that one of the authors, considering all</p> <p>4 the additional data that's accumulated, would -- has</p> <p>5 made a different conclusion at this point in time.</p> <p>6 Q. And the author you're referring to there is</p> <p>7 the author that we were discussing as a paid expert in</p> <p>8 this case; correct?</p> <p>9 MS. PARFITT: Objection. Form.</p> <p>10 THE WITNESS: Yes. We established he</p> <p>11 is a paid expert and, at the same time, a very</p> <p>12 well-respected epidemiologist.</p> <p>13 BY MR. JAMES:</p> <p>14 Q. There's also a pooled analysis that you</p> <p>15 looked at to inform your opinions in this case;</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And the pooled analysis is the Terry</p> <p>19 2013 paper?</p> <p>20 A. That is correct.</p> <p>21 Q. Okay. Did the Terry 2013 paper conclude</p> <p>22 cause?</p> <p>23 MS. PARFITT: Objection. Form.</p> <p>24 BY MR. JAMES:</p> <p>25 Q. It's yes or no.</p>	<p>1 The authors there are reserving judgment on</p> <p>2 causation; correct?</p> <p>3 MS. PARFITT: Objection. Form.</p> <p>4 THE WITNESS: I don't think that that</p> <p>5 is how I would necessarily interpret that.</p> <p>6 BY MR. JAMES:</p> <p>7 Q. Okay.</p> <p>8 A. I think that, first of all, basically, any</p> <p>9 scientific paper concludes with "more work is needed."</p> <p>10 And so it's talking about, you know, trying to advance</p> <p>11 scientific knowledge by understanding the biological</p> <p>12 mechanism.</p> <p>13 But I don't see anything -- any statement</p> <p>14 there related to causal. It says "small to moderate</p> <p>15 increased risk of ovarian cancer." And as I've stated</p> <p>16 previously, basically, when we talk about risk</p> <p>17 factors, we are thinking that this is something that</p> <p>18 causes this cancer.</p> <p>19 Q. So in your professional opinion, the word</p> <p>20 "risk factor" is equivalent to "causation"?</p> <p>21 A. Not always equivalent. And if I may give an</p> <p>22 example.</p> <p>23 Women who have higher educational level are</p> <p>24 at increased risk for breast cancer. And so higher</p> <p>25 education level, we might describe it as a risk factor</p>

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<p>1 for breast cancer. But, clearly, going to college is</p> <p>2 not going to cause breast cancer. It's the other</p> <p>3 factors that are associated with it, like your</p> <p>4 childbearing patterns, alcohol use, other things.</p> <p>5 But when we talk about a risk factor and</p> <p>6 there is a plausible biological mechanism to get from</p> <p>7 that exposure to cancer, I think that "risk factor"</p> <p>8 and "cause" are pretty synonymous.</p> <p>9 Q. But to say something is associated in</p> <p>10 epidemiologic literature is not to say that it's</p> <p>11 causal.</p> <p>12 Do you agree with that?</p> <p>13 MS. PARFITT: Objection.</p> <p>14 THE WITNESS: Yes. That's kind of</p> <p>15 epi 101, that everything that is associated is not</p> <p>16 necessarily a cause.</p> <p>17 BY MR. JAMES:</p> <p>18 Q. To reach a causal conclusion, it's -- one</p> <p>19 must undertake a more in-depth analysis; correct?</p> <p>20 A. As I did for this, and as all of us in this</p> <p>21 room are well aware, the Bradford Hill framework is a</p> <p>22 framework for taking the data and leading to making a</p> <p>23 judgment on causality.</p> <p>24 Q. So if a paper refers to something as a risk</p> <p>25 factor or a potential risk factor or a modifiable risk</p>	<p>1 meta-analyses.</p> <p>2 Q. Are you aware of any flaws in the</p> <p>3 Penninkilampi study?</p> <p>4 MS. PARFITT: Objection. Form.</p> <p>5 THE WITNESS: Overall, I felt like it</p> <p>6 seemed to be a very well done meta-analysis. When we</p> <p>7 look at judgments of meta-analyses, we like to see</p> <p>8 things like, you know, what were the search terms they</p> <p>9 used? What were the criteria for including or</p> <p>10 excluding studies? Were the study questions defined</p> <p>11 in advance?</p> <p>12 And when I look through all of that,</p> <p>13 I judged it overall to be a very well done</p> <p>14 meta-analysis.</p> <p>15 BY MR. JAMES:</p> <p>16 Q. And so your answer to the question that</p> <p>17 I asked is no; correct?</p> <p>18 MS. PARFITT: Objection.</p> <p>19 THE WITNESS: I -- I don't see any</p> <p>20 serious problems with any -- you characterized it as</p> <p>21 "flaws." I don't -- I don't see anything that I would</p> <p>22 characterize as a flaw in their methodology.</p> <p>23 BY MR. JAMES:</p> <p>24 Q. If you look at page 47 with me, Dr. Moorman,</p> <p>25 in the "Conclusions" section.</p>
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<p>1 factor, that terminology by itself does not suggest</p> <p>2 that the authors of that paper have concluded</p> <p>3 causation; correct?</p> <p>4 A. I -- I think that I have answered that</p> <p>5 question already.</p> <p>6 When they're -- if they refer to it as a</p> <p>7 risk factor, they may or may not have gone through the</p> <p>8 full Bradford Hill evaluation of it. And then, also,</p> <p>9 some things that we refer to as risk factors, where</p> <p>10 there is not a plausible biological mechanism, we</p> <p>11 wouldn't equate risk factor and cause in that</p> <p>12 situation as well.</p> <p>13 Q. So you -- returning back to the Penninkilampi</p> <p>14 meta-analysis, which I believe will be somewhere in</p> <p>15 that pile --</p> <p>16 A. Mm-hmm.</p> <p>17 Q. -- you cite Penninkilampi 14 times in your</p> <p>18 report.</p> <p>19 Were you aware of that?</p> <p>20 A. I don't know how many times I've cited it.</p> <p>21 Q. It's one of the most cited articles in your</p> <p>22 report.</p> <p>23 Were you aware of that?</p> <p>24 A. I know that I referred to it frequently</p> <p>25 because it is one of the most up-to-date, most recent</p>	<p>1 The conclusions section, I think you had</p> <p>2 previously read in the first sentence of the</p> <p>3 conclusions, the percentage increased risk reported in</p> <p>4 the paper.</p> <p>5 The second sentence says (as read):</p> <p>6 "While the results of case-control</p> <p>7 studies are prone to recall bias,</p> <p>8 especially with intense media</p> <p>9 attention following the</p> <p>10 commencement of litigation in</p> <p>11 2014, the confirmation of an</p> <p>12 association in cohort studies</p> <p>13 between perineal talc use and</p> <p>14 serous invasive ovarian cancer is</p> <p>15 suggestive of a causal</p> <p>16 association."</p> <p>17 Do you see where I was reading?</p> <p>18 A. Yes, I do.</p> <p>19 Q. Okay. So here we see that Penninkilampi is</p> <p>20 acknowledging the recall bias problems of the</p> <p>21 case-control studies; correct?</p> <p>22 A. They are acknowledging that it is a</p> <p>23 possibility.</p> <p>24 Q. Okay.</p> <p>25 A. Okay.</p>

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<p>1 MS. PARFITT: Wait. Are you still -- 2 thank you. 3 Please, finish. 4 THE WITNESS: Yes. And, you know, this 5 is, again, one of the things that I addressed in my 6 report. I very carefully considered recall bias and 7 how it could have contributed or not to the elevated 8 risk that has been seen across so many studies. 9 BY MR. JAMES: 10 Q. And one of the -- so within the sentence 11 "after acknowledging the recall bias" that we just 12 discussed, the Penninkilampi authors emphasize the 13 confirmation of an association in cohort studies. 14 Do you see that? 15 A. I do. 16 Q. Okay. Are there cohort studies that support 17 the association? 18 A. There are three cohort studies that have 19 examined talc use and ovarian cancer, and you're 20 probably very much aware of them: the Gonzalez study, 21 the Houghton -- which was from the Sister Study -- the 22 Houghton study, which was the Women's Health 23 Initiative; and the Nurses' Health Study, which has 24 been published in several of them. 25 And as they indicate in here, when you look</p>	<p>1 entirely sure of their rationale for why they looked 2 at one rather than the other. There were some 3 differences between the studies; like the later study, 4 the unexposed group was actually women who had used it 5 for less than once a week rather than never used. And 6 so they don't really go into the detail why they made 7 that decision. 8 But investigators will make a judgment 9 sometimes about which of a -- which studies to include 10 when there's more than one publication from a given 11 study. 12 Q. And do you know that with respect to the NHS 13 cohort, they have published two studies arising from 14 the NHS cohort looking at the issue of talc and the 15 ovarian cancer association; correct? 16 MS. PARFITT: Objection. Form. 17 THE WITNESS: They actually -- they 18 have published two studies, and data from the Nurses' 19 Health Study was also included in at least one other 20 publication. I believe Cramer was -- I'm not sure if 21 he was the first author or one of the authors where 22 they combined data. 23 BY MR. JAMES: 24 Q. The NHS cohort has published two papers with 25 respect to the talc/ovarian cancer association;</p>
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<p>1 at the studies that reported on invasive serous -- and 2 if you will give me just a second here -- find it on 3 this paper. Okay. 4 When they report in Table 2 that combining 5 the two studies that reported on the histologic 6 subtypes, there was a significantly increased risk of 7 serous invasive cancer in the cohort studies as well 8 in the case-control studies. 9 Q. Sorry. 10 A. Okay. 11 Q. You did pause there. 12 A. I did. 13 The one study that really found no 14 association whatsoever with talc was the Gonzalez 15 study, the Sister Study, that has numerous problems 16 with it, most specifically in their assessment of the 17 talc exposure, the sample size, the duration of 18 follow-up. 19 Q. And returning to my question about this 20 article, were you aware that the Penninkilampi authors 21 didn't factor in the Gates 2010 data at all? 22 A. When one does a meta-analysis, sometimes when 23 data are reported in a couple of reports, you have to 24 make a decision about which one to include. 25 I believe they used data from the -- I'm not</p>	<p>1 correct? 2 A. I just answered the question. It's -- data 3 from it was also in another -- in another publication. 4 Q. The Gertig 2000 paper reported on the 5 talc/ovarian cancer association; correct? 6 A. Yes. 7 Q. And that's an NHS publication; correct? 8 A. It is. 9 Q. The Gates 2010 paper reported on talc/ovarian 10 cancer association; correct? 11 A. That is correct. 12 Q. And that's an NHS publication; correct? 13 A. Correct. 14 Q. An NHS publication of 2010 offered an 15 additional ten years of follow-up to the talc/ovarian 16 cancer hypothesis; correct? 17 MS. PARFITT: Objection. Form. 18 THE WITNESS: It was additional 19 follow-up, but no update on exposure during that 20 time -- period of follow-up. 21 BY MR. JAMES: 22 Q. For that period of follow-up, they followed 23 the study participants for an additional ten years; 24 correct? 25 MS. PARFITT: Objection. Form.</p>

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<p>1 THE WITNESS: Yes. I answered that 2 already. Yes. 3 BY MR. JAMES: 4 Q. And you agree more follow-up for a cohort is 5 better; correct? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: In general, longer 8 follow-up would be desirable. However, when they're 9 not updating exposure information, that could -- that 10 creates a bias, a possible bias. 11 BY MR. JAMES: 12 Q. Do you think the 2010 data and the Gates 13 paper with respect to the talc ovarian cancer issue is 14 superior to the 2000 data in the Gertig 2000 paper? 15 MS. PARFITT: Objection. Form. 16 THE WITNESS: I already made the point 17 that how they define the unexposed group was different 18 between the two studies; and so including some women 19 who had low levels of exposure in their unexposed 20 group, that could potentially have had the effect of 21 attenuating the association. 22 And so, you know, longer follow-up is 23 generally better, but some of the other things they 24 did, that's -- they were not so good. 25</p>	<p>1 Q. So one of your complaints -- 2 A. So I -- 3 Q. Sorry. 4 A. Okay. 5 Q. One of your issues with the cohort studies is 6 lack of follow-up; correct? 7 A. For -- yes, for -- there are -- it's one of 8 several concerns I have about the cohort studies. 9 Q. And the Penninkilampi study did not factor in 10 the additional period of follow-up through the 2010 11 paper; correct? 12 A. I don't believe they did. I think they went 13 with the earlier study. 14 Q. In fact, they didn't even cite to the Gates 15 2010 data, did they? 16 MS. PARFITT: Objection. 17 THE WITNESS: No, they -- they didn't. 18 BY MR. JAMES: 19 Q. And they didn't offer any explanation about 20 why they went with the earlier study, did they? 21 A. Not that I recall. 22 Q. And do you understand that in the 2010 NHS 23 paper through Gates, the association with serous 24 ovarian cancer washed out? 25 MS. PARFITT: Objection to form.</p>
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<p>1 BY MR. JAMES: 2 Q. Elsewhere in your report, you do complain 3 about lack of follow-up in the cohort studies, don't 4 you? 5 A. I do mention that as one of the limitations, 6 yes. 7 Q. And you specifically discuss the NHS cohort 8 as having a period of -- I believe you say it's 9 14 years; is that right? 10 A. From -- yeah. I -- I can't remember 11 specifically. It's from the 1980s to -- I don't 12 remember the exact date of the last -- the last date 13 of follow-up in their papers. 14 Q. And, again, that's the exposure period that 15 Penninkilampi is looking at as well; correct? 16 Or excuse me, not the exposure period, the 17 period of time that they follow the study 18 participants; correct? 19 Penninkilampi is looking at from 20 questionnaire to 2000; correct? 21 A. Correct. 22 Q. Okay. And when you say in your report that 23 the NHS study has a 14-year follow-up period, that's 24 what you're looking at too, as well; correct? 25 A. Right. From the time of exposures --</p>	<p>1 THE WITNESS: "Washed out," I don't 2 like that term. But again, I fully acknowledge that 3 the later study showed weaker associations, yes. 4 BY MR. JAMES: 5 Q. And the association for serous invasive 6 ovarian cancer in the Gates 2010 paper was not 7 statistically significant; correct? 8 A. I believe that is correct. 9 Q. So when you include the critique in your 10 report about the follow-up being a 14-year period, you 11 also, like Penninkilampi, aren't crediting the 12 additional ten years of follow-up that the Gates paper 13 published on; correct? 14 MS. PARFITT: Objection to form. 15 THE WITNESS: "Aren't crediting the 16 additional ten years of follow-up." 17 You know, as I have stated before, when 18 people do meta-analyses, they will make decisions 19 about which studies to include. I acknowledge that 20 Penninkilampi didn't describe in detail why they went 21 with the Gertig rather than a later study. 22 My understanding, however, is that other 23 people -- other meta-analyses have looked at -- have 24 included the later study, and the overall conclusions 25 were not changed in any real way.</p>

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<p style="text-align: right;">Page 194</p> <p>1 BY MR. JAMES: 2 Q. Well, Penninkilampi, you say, didn't describe 3 in detail about why they went with the earlier study, 4 but, in truth, they didn't describe it at all. 5 MS. PARFITT: Objection. 6 THE WITNESS: That's -- that's correct. 7 BY MR. JAMES: 8 Q. And when you refer to other studies that 9 have, in fact, looked at the Gates 2010 cohort data 10 that provides a longer period of follow-up, those 11 papers have necessarily noted that the serous 12 relationship found in Gertig 2000 disappeared in 2010; 13 correct? 14 MS. PARFITT: Objection. Form. 15 THE WITNESS: Can you -- can we -- tell 16 me which -- specifically which article you're -- 17 BY MR. JAMES: 18 Q. Sure. Let's turn to the Berge article. 19 A. Okay. 20 Q. The Berge article was marked as 21 Exhibit No. 21. And you have it before you, Doctor? 22 A. I do. 23 Q. Okay. And if you turn to Figure 2, which is 24 on page 254, do you see that there that in the forest 25 plot, they have listed the cohort studies at the</p>	<p style="text-align: right;">Page 196</p> <p>1 BY MR. JAMES: 2 Q. They're heterogeneous. Did I pronounce that 3 correctly? 4 A. No. Heterogeneous. 5 Q. Heterogeneous. Thank you. I figured I got 6 that wrong. 7 So what they're saying there is that the 8 results by the study design are different; right? 9 A. That's -- yes, that's what they are saying. 10 Q. And here we see, again, that this study used 11 the more recent data; correct? 12 MS. PARFITT: Objection. Form. 13 THE WITNESS: It used the more recent 14 publication from the Nurses' Health Study, yes. 15 BY MR. JAMES: 16 Q. Which includes the more recent data; correct? 17 MS. PARFITT: Objection. 18 THE WITNESS: Yes. 19 BY MR. JAMES: 20 Q. On page 8 of your report, Dr. Moorman, you 21 say at the bottom paragraph (as read): 22 "Cohort studies and case-control 23 studies each have advantages and 24 disadvantages for assessing talc 25 as a risk factor for ovarian</p>
<p style="text-align: right;">Page 195</p> <p>1 bottom; correct? 2 A. Correct. 3 Q. Okay. And there they report data from the 4 Gates 2010 study; correct? 5 A. Correct. 6 Q. Okay. They do not report the data from the 7 Gertig 2000 paper; correct? 8 A. That is correct. 9 Q. And if you look at the conclusions of the 10 Berge authors -- and we talked about this before -- 11 but if you look at the abstract of the paper, 12 Dr. Moorman, the authors say (as read): 13 "The heterogeneity of results by 14 study design, however, detracts 15 from a causal interpretation of 16 this association." 17 Do you see that? 18 A. Yes. You've asked that before. Yes. 19 Q. And what the authors there are saying is that 20 the results from the case-control studies, the 21 meta-analyses of the case-control studies, and the 22 results of the meta-analyses of the cohort studies are 23 different; right? 24 MS. PARFITT: Objection. 25 THE WITNESS: They -- yes.</p>	<p style="text-align: right;">Page 197</p> <p>1 cancer, and one study design is 2 not clearly superior to the 3 other." 4 Do you see where I was reading that? 5 A. Yes, I do. 6 Q. So your expert opinion in this case is that 7 the cohort studies on talc ovarian cancer and the 8 case-control studies on talc ovarian cancer are on 9 equal footing? 10 A. I think -- again, using terminology like 11 "equal footing," it's -- I wouldn't really describe it 12 like that. 13 I think that case-control studies and cohort 14 studies are both well-established, well-accepted 15 methods for studying cancer epidemiology. There are 16 strengths and weaknesses to each design, as I have 17 indicated here. And some of them very -- some of the 18 strengths and weaknesses are very specific to this 19 exposure and outcome. 20 Q. Doesn't the body of talc ovarian cancer 21 literature that you've looked at for your MDL opinions 22 emphasize the importance of cohort data on the issue? 23 MS. PARFITT: Objection. Form. 24 THE WITNESS: I considered all of the 25 epidemiologic data; and when we look at the body of</p>

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<p>1 literature, more of the literature comes from 2 case-control studies than from cohort studies. So all 3 of the data are important. There just happen to be 4 more case-control studies than cohort studies. 5 BY MR. JAMES: 6 Q. But your testimony is that the cohorts are 7 not superior to the case-controls, and the 8 case-controls are not superior to the cohorts; 9 correct? 10 A. As I describe in my report -- the same page, 11 I say (as read): 12 "Rather than making a judgment 13 based only on the overall study 14 design, the evaluation and 15 interpretation of the findings of 16 the studies must consider the 17 strengths and weaknesses of the 18 individual studies." 19 And I think that I did consider that. 20 I considered strengths and weaknesses of the cohort 21 studies. I considered strengths and weaknesses of the 22 case-control studies. 23 Q. And you're not claiming that the study design 24 of these studies -- the cohort versus the 25 case-control -- one is superior to the other? You're</p>	<p>1 And it's the number of cases rather than the overall 2 size of the cohort that contributes to the statistical 3 power. And that doesn't address all the other 4 problems with that study. 5 But sometimes people will mistakenly say 6 these large studies -- you know, this large study, 7 40,000 people, and they didn't find an association. 8 But they're not looking into all the limitations of 9 that particular study. 10 BY MR. JAMES: 11 Q. Okay, Dr. Moorman, I'm going to object to the 12 nonresponsive nature of your answer. 13 A. I -- I think that I was responsive, but 14 please ask your question again. 15 Q. Okay. So the question that I asked you is 16 whether you are aware that the body of literature that 17 you've looked at has generally emphasized the 18 importance of cohort data on this topic. The answer 19 is yes or the answer is no. 20 MS. PARFITT: The answer is -- first, 21 I object to the question. And the witness has 22 answered the question several times. Your time. 23 You're on your clock. 24 BY MR. JAMES: 25 Q. Are you aware that the body of literature has</p>
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<p>1 not claiming that? 2 MS. PARFITT: Objection. Asked and 3 answered several times. 4 THE WITNESS: Right. I -- again, 5 I think that I have answered that, that they -- the 6 study designs are both well-accepted study designs; 7 they have advantages and disadvantages; and so you 8 have to look at some of the specific characteristics 9 of the individual studies. 10 BY MR. JAMES: 11 Q. And so the body of talc literature that 12 you've looked at, whether it be cohort studies, 13 meta-analyses, case-control studies, are you aware 14 that that body of literature has generally emphasized 15 the importance of cohort data on this topic? 16 MS. PARFITT: Objection. Misstates the 17 record -- scientific record. 18 THE WITNESS: I am aware -- I have read 19 some studies that mistakenly say that the cohort 20 studies, because they involve 40,000 or 60,000 people, 21 that they provide more of the evidence than all the 22 case-control studies, which are generally smaller. 23 However, just, again, to take the example of 24 the Gonzalez sisters study, that's a cohort with 25 40,000 people in it, but there were only 154 cases.</p>	<p>1 emphasized the importance of cohort data? Are you 2 aware of that? Yes or no? 3 MS. PARFITT: Objection. 4 THE WITNESS: I -- I disagree that -- 5 your characterization of it. 6 BY MR. JAMES: 7 Q. Then, the answer is no. 8 A. No. You asked am I aware -- 9 Q. The answer is yes or it's no, Dr. Moorman. 10 I have limited time to ask questions today. 11 Were you aware -- are you aware that the 12 body of literature on talc and ovarian cancer has 13 emphasized the importance of cohort data on this 14 topic? 15 MS. PARFITT: Objection. Form. 16 THE WITNESS: I don't think -- 17 MS. PARFITT: Asked and answered. 18 THE WITNESS: -- the statement is true. 19 I think that the -- 20 BY MR. JAMES: 21 Q. So then the answer is no. 22 MS. PARFITT: Stop. Let her answer. 23 THE WITNESS: No. You're asking me if 24 I'm aware -- 25 MS. PARFITT: Why do you ask her the</p>

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<p style="text-align: right;">Page 202</p> <p>1 same question?</p> <p>2 THE WITNESS: -- that this has</p> <p>3 emphasized that. And I don't think that is it at all.</p> <p>4 I think that the body of literature</p> <p>5 emphasizes again and again and again that of the</p> <p>6 roughly 25 to 30 studies, only three of them are</p> <p>7 cohort studies.</p> <p>8 It's part of the data on the topic, but it's</p> <p>9 just part of it. So to say that it has emphasized the</p> <p>10 importance of cohort data, I don't agree with that</p> <p>11 statement.</p> <p>12 BY MR. JAMES:</p> <p>13 Q. I marked the Houghton WHI study as</p> <p>14 Exhibit No. 25, and I'm going to hand you two copies.</p> <p>15 (Exhibit No. 25 was marked for identification.)</p> <p>16 THE WITNESS: Thank you.</p> <p>17 BY MR. JAMES:</p> <p>18 Q. All right. Dr. Moorman, you see here in the</p> <p>19 abstract, the "Background" section of the paper, the</p> <p>20 authors of the WHI study in 2014 say that (as read):</p> <p>21 "The purpose of this analysis was</p> <p>22 to assess perineal powder use and</p> <p>23 risk of ovarian cancer</p> <p>24 prospectively."</p> <p>25 Correct?</p>	<p style="text-align: right;">Page 204</p> <p>1 exposure."</p> <p>2 Do you see where I read that?</p> <p>3 A. I do.</p> <p>4 Q. Okay. Again, do you agree with that</p> <p>5 statement as a general proposition?</p> <p>6 A. I would like to point out there are --</p> <p>7 potential reason, a potential for an overestimation.</p> <p>8 And in my own report, I acknowledge the potential for</p> <p>9 recall bias, and I go back to explain why I don't</p> <p>10 think that recall bias is a full explanation for this</p> <p>11 association.</p> <p>12 Q. Nevertheless, you will agree with me that the</p> <p>13 authors of this paper are acknowledging the importance</p> <p>14 of cohort data? Agree?</p> <p>15 MS. PARFITT: Objection.</p> <p>16 THE WITNESS: As you would expect the</p> <p>17 investigators on a cohort study to do.</p> <p>18 BY MR. JAMES:</p> <p>19 Q. And the answer was yes --</p> <p>20 A. Yes.</p> <p>21 Q. -- comma, as you would expect?</p> <p>22 MS. PARFITT: Objection.</p> <p>23 THE WITNESS: Yes.</p> <p>24 MR. JAMES: I'm going to mark as the</p> <p>25 next exhibit the Gertig 2000 paper, which is</p>
<p style="text-align: right;">Page 203</p> <p>1 A. That is what it says, yes.</p> <p>2 Q. Okay. And if we look towards page 5, we see,</p> <p>3 at the top of the left-hand column, the authors there</p> <p>4 emphasize (as read):</p> <p>5 "The prospective nature of our</p> <p>6 study would eliminate the</p> <p>7 potential for recall bias."</p> <p>8 Do you see that?</p> <p>9 A. I do see that.</p> <p>10 Q. Do you agree with that general proposition?</p> <p>11 "Yes" or "no"?</p> <p>12 A. It eliminates the potential for recall bias.</p> <p>13 It does not eliminate the potential for inaccurate</p> <p>14 recall.</p> <p>15 Q. And if you look at page 4, it's the preceding</p> <p>16 set of sentences, the authors note -- quote -- at the</p> <p>17 bottom of the right column (as read):</p> <p>18 "One potential reason that</p> <p>19 case-control studies have found</p> <p>20 slight increases in risk is the</p> <p>21 potential for an overestimation of</p> <p>22 the true association due to recall</p> <p>23 bias, because the participants are</p> <p>24 aware of their ovarian cancer</p> <p>25 status when reporting powder</p>	<p style="text-align: right;">Page 205</p> <p>1 Exhibit No. 26.</p> <p>2 (Exhibit No. 26 was marked for identification.)</p> <p>3 BY MR. JAMES:</p> <p>4 Q. Again, this is the NHS 2000 paper; correct?</p> <p>5 A. That is correct.</p> <p>6 Q. And we see that in the abstract of this</p> <p>7 cohort paper, the authors state at the -- well, it's</p> <p>8 not in the abstract -- it's right above the "Methods"</p> <p>9 section, the authors state (as read):</p> <p>10 "Despite the relative consistency</p> <p>11 among studies, the limited</p> <p>12 supporting biologic evidence,</p> <p>13 together with the possibility of</p> <p>14 recall and selection bias in</p> <p>15 case-control studies, has raised</p> <p>16 questions about the plausibility</p> <p>17 of the association. We,</p> <p>18 therefore, prospectively examined</p> <p>19 the relationship between perineal</p> <p>20 talc use and ovarian cancer risk</p> <p>21 in a large cohort of US women."</p> <p>22 Do you see where I read that?</p> <p>23 A. Yes, I do.</p> <p>24 Q. And again, methodologically, the authors of</p> <p>25 this cohort paper are emphasizing the importance of</p>

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<p>1 cohort data on the topic; correct?</p> <p>2 MS. PARFITT: Objection.</p> <p>3 THE WITNESS: Yes. Again, they</p> <p>4 emphasize the importance of doing it prospectively, as</p> <p>5 you would expect the investigators on a cohort study</p> <p>6 to do.</p> <p>7 BY MR. JAMES:</p> <p>8 Q. Do you think that's just because there's some</p> <p>9 sort of subjective bias the authors of that cohort</p> <p>10 paper have towards cohorts? Do you think that's just</p> <p>11 their personal opinion?</p> <p>12 MS. PARFITT: Objection.</p> <p>13 THE WITNESS: I have no way of knowing</p> <p>14 what their opinion is.</p> <p>15 BY MR. JAMES:</p> <p>16 Q. A number of the meta-analyses that we've</p> <p>17 looked at today and that you looked at to inform your</p> <p>18 report have also talked about the benefits of cohort</p> <p>19 data. And I've asked that question before, and that's</p> <p>20 where we -- that's where we sort of ran into issues,</p> <p>21 so I'll just strike that question.</p> <p>22 If you can turn to -- back to the</p> <p>23 Penninkilampi study. And the Penninkilampi study is</p> <p>24 the recent meta-analysis that you cited 14 times in</p> <p>25 your report; correct?</p>	<p>1 again stressing the desire for cohort data on this</p> <p>2 topic; correct?</p> <p>3 MS. PARFITT: Objection. Misstates the</p> <p>4 evidence.</p> <p>5 THE WITNESS: When -- if we were to</p> <p>6 look at a cohort study where women were enrolled in</p> <p>7 the study early in their life when they started using</p> <p>8 talc and they were followed throughout their life and</p> <p>9 exposure information was updated throughout the period</p> <p>10 of follow-up and you followed them for 50 years, that</p> <p>11 would be a wonderful way -- a stronger design than to</p> <p>12 do a case-control study. So I could not disagree with</p> <p>13 that.</p> <p>14 But we're being asked to make a judgment on</p> <p>15 the data that we have here -- here and now, not</p> <p>16 something that's decades away.</p> <p>17 BY MR. JAMES:</p> <p>18 Q. Do you agree that case-control studies are</p> <p>19 low-level evidence?</p> <p>20 A. No, I do not agree with that.</p> <p>21 Q. Do you know that the Penninkilampi authors</p> <p>22 referred to case-control studies as low-level</p> <p>23 evidence?</p> <p>24 A. I see that in their paper.</p> <p>25 Q. Do you --</p>
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<p>1 MS. PARFITT: Objection. Form.</p> <p>2 THE WITNESS: As stated below -- or</p> <p>3 stated above, I have cited it. I don't know how many</p> <p>4 times.</p> <p>5 BY MR. JAMES:</p> <p>6 Q. And meta-analyses also are what you refer to</p> <p>7 in your report as some of the strongest evidence;</p> <p>8 correct?</p> <p>9 A. Yes, that is correct.</p> <p>10 Q. Okay. And so the authors of this</p> <p>11 meta-analysis, on page 47 in the conclusion section,</p> <p>12 which we have looked at already, again note that</p> <p>13 case-control studies are "prone to recall bias";</p> <p>14 right?</p> <p>15 A. That's what it says, yes.</p> <p>16 Q. Okay. And then if you continue on past the</p> <p>17 section that we've already read -- and actually, it</p> <p>18 begins at the bottom of page 47 and carries to 48 --</p> <p>19 but the authors state (as read):</p> <p>20 "Additional epidemiologic evidence</p> <p>21 from prospective studies with</p> <p>22 attention to effects within</p> <p>23 ovarian cancer subtype is</p> <p>24 warranted."</p> <p>25 So here the authors of Penninkilampi are</p>	<p>1 A. I --</p> <p>2 Q. I'm sorry.</p> <p>3 A. I will disagree with that. It's -- just</p> <p>4 using the example of my own study, the AACES study.</p> <p>5 Of all the studies that have looked at talc and</p> <p>6 ovarian cancer, I believe that one is the one that has</p> <p>7 been most recently funded. So about 2009, 2010. It's</p> <p>8 quite an expensive study, and I can't imagine that the</p> <p>9 National Cancer Institute would have invested that</p> <p>10 much money in the study if they thought that we were</p> <p>11 only going to get low-level evidence.</p> <p>12 MS. PARFITT: Scott, we've been going</p> <p>13 about an hour and ten.</p> <p>14 You may want to keep going? Just let me</p> <p>15 know.</p> <p>16 THE WITNESS: I could use a break.</p> <p>17 MR. JAMES: May I finish this line? Is</p> <p>18 that okay with you?</p> <p>19 THE WITNESS: Yes.</p> <p>20 MR. JAMES: Everyone?</p> <p>21 MS. PARFITT: Sure.</p> <p>22 BY MR. JAMES:</p> <p>23 Q. Dr. Moorman, if you can turn with me to the</p> <p>24 Langseth study. It's Exhibit 22. And this will be</p> <p>25 the last series of questions, and then we'll take our</p>

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<p style="text-align: right;">Page 210</p> <p>1 break.</p> <p>2 A. Langseth -- okay. The exhibit number is</p> <p>3 incorrect.</p> <p>4 Q. Oh, you're right. And I'm going to fix that</p> <p>5 at break. Thank you.</p> <p>6 A. Okay.</p> <p>7 Q. If you turn with me to page -- well, you</p> <p>8 don't have to turn. It's page 358. It's the first</p> <p>9 page of the article. And, again, Langseth is one of</p> <p>10 the meta-analyses upon which you rely; correct?</p> <p>11 A. Correct.</p> <p>12 Q. And the meta-analyses authors here say, in</p> <p>13 the left-hand column at the bottom, the second</p> <p>14 sentence of the bottom paragraph, they say (as read):</p> <p>15 "In the cohort study, arguably the</p> <p>16 strongest study because of its</p> <p>17 partly prospective ascertainment</p> <p>18 of exposure, there was no</p> <p>19 association between cosmetic talc</p> <p>20 use and risk of all subtypes of</p> <p>21 ovarian cancer combined."</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. You agree with the Langseth authors</p> <p>25 that the cohort study is arguably the strongest study</p>	<p style="text-align: right;">Page 212</p> <p>1 Q. And you cite Narod for your comments about</p> <p>2 power in the cohorts; correct?</p> <p>3 A. Yes.</p> <p>4 Q. Have you analyzed the calculations performed</p> <p>5 by Narod? Have you separately analyzed his</p> <p>6 calculations?</p> <p>7 A. No, I did not.</p> <p>8 Q. Have you considered any other commentaries or</p> <p>9 articles looking at the issue of power in the cohort</p> <p>10 studies in the talc ovarian cancer literature?</p> <p>11 A. I -- I'm trying to remember specifically. It</p> <p>12 seems like the Sister Study might have mentioned power</p> <p>13 as a limitation of their study because of the number</p> <p>14 of cases.</p> <p>15 Q. Did you consider -- let me just hand this to</p> <p>16 you. We already have it marked. It's the Berge</p> <p>17 article, which is Exhibit 21.</p> <p>18 A. Okay.</p> <p>19 Q. And I'm turning to page 253. And at the</p> <p>20 far -- the right column, top paragraph, and halfway</p> <p>21 down through that paragraph, the authors state</p> <p>22 (as read):</p> <p>23 "It should be noted that the</p> <p>24 cohort studies included in the</p> <p>25 meta-analyses comprised a total of</p>
<p style="text-align: right;">Page 211</p> <p>1 because of its prospective nature?</p> <p>2 A. I really can't say that I agree with that,</p> <p>3 because the prospective aspect of it is certainly a</p> <p>4 positive for the study, but the way they did exposure</p> <p>5 assessment kind of weakened the study.</p> <p>6 So I think that there were some very well</p> <p>7 done case-control studies, so I wouldn't necessarily</p> <p>8 say this was the strongest study.</p> <p>9 MR. JAMES: And now is a good time for</p> <p>10 the break.</p> <p>11 THE WITNESS: Okay.</p> <p>12 MR. JAMES: Thank you.</p> <p>13 THE VIDEOGRAPHER: Going off record at</p> <p>14 3:02 p.m.</p> <p>15 (Recess taken from 3:02 p.m. to 3:16 p.m.)</p> <p>16 THE VIDEOGRAPHER: Back on record at</p> <p>17 3:16 p.m.</p> <p>18 BY MR. JAMES:</p> <p>19 Q. Dr. Moorman, on page 25 of your report, you</p> <p>20 make a comment about power and the cohort studies;</p> <p>21 correct?</p> <p>22 A. Can you --</p> <p>23 Q. It's the bottom of first paragraph, where you</p> <p>24 cite the Narod article.</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 213</p> <p>1 429 cases of ovarian cancer</p> <p>2 exposed to genital talc and 943</p> <p>3 unexposed cases. The statistical</p> <p>4 power of the meta-analysis of</p> <p>5 these cohort studies to detect a</p> <p>6 relative risk of 1.25, similar to</p> <p>7 the result of meta-analyses of</p> <p>8 case-control studies, was .99.</p> <p>9 Thus low power of cohort studies</p> <p>10 cannot be invoked as an</p> <p>11 explanation of the heterogeneity</p> <p>12 of results."</p> <p>13 You see where I was reading?</p> <p>14 A. I do.</p> <p>15 Q. Have you considered this portion of the Berge</p> <p>16 article before?</p> <p>17 A. I have looked at this article, and I have</p> <p>18 considered all aspects of it, as I did all of the</p> <p>19 other meta-analyses and articles.</p> <p>20 Q. You did not cite the Berge article with</p> <p>21 regard to the issue of power in your report; correct?</p> <p>22 MS. PARFITT: Objection. Form.</p> <p>23 THE WITNESS: No, I -- I did not.</p> <p>24 BY MR. JAMES:</p> <p>25 Q. Okay. And why is that?</p>

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<p>1 A. I can't cite any specific reason.</p> <p>2 Q. Is that because this conflicts with your</p> <p>3 litigation opinion on power?</p> <p>4 MS. PARFITT: Objection. Form.</p> <p>5 THE WITNESS: No. I -- I don't -- that</p> <p>6 was not my reason, no.</p> <p>7 BY MR. JAMES:</p> <p>8 Q. Do you have any reason to disagree with the</p> <p>9 power analysis set forth in the Berge paper?</p> <p>10 A. I -- I don't have a reason to disagree with</p> <p>11 the power issue, but I think that it's only one part</p> <p>12 of the picture, that there are other factors that</p> <p>13 could contribute to differences in the findings</p> <p>14 between the cohort studies and the case-control</p> <p>15 studies.</p> <p>16 Q. With respect to this precise power</p> <p>17 calculation in the Berge paper, do you have any</p> <p>18 criticisms of this power calculation?</p> <p>19 A. They do not provide much detail on how they</p> <p>20 calculated it, so there's really -- I can't say if</p> <p>21 they did it correctly or not. But I -- I just can't</p> <p>22 comment on it. It's just a single sentence there.</p> <p>23 Q. Similar to the Narod sentence that you</p> <p>24 reviewed?</p> <p>25 A. I --</p>	<p>1 but with respect to the issue of follow-up -- it's the</p> <p>2 paragraph above the Narod comment.</p> <p>3 Do you see where I am?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And there, we talk about -- excuse me.</p> <p>6 There, you talk about the follow-up for the cohort</p> <p>7 studies; correct?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And with respect to the NHS follow-up,</p> <p>10 there is where you report 14 years of follow-up;</p> <p>11 right?</p> <p>12 A. Correct.</p> <p>13 Q. And as we discussed earlier today, that does</p> <p>14 not account for the additional ten years of data as</p> <p>15 reflected by the Gates 2010 paper; correct?</p> <p>16 A. What I am referring here, I'm describing the</p> <p>17 three cohort studies in the most recent meta-analyses</p> <p>18 and what they reported in that meta-analysis --</p> <p>19 Q. Understood.</p> <p>20 A. Okay.</p> <p>21 Q. So you're referring there to the</p> <p>22 Penninkilampi meta-analysis; correct?</p> <p>23 A. I believe that is the case. Let me check the</p> <p>24 reference. Yes.</p> <p>25 Q. So Penninkilampi reports the 14 years of</p>
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<p>1 Q. Let me rephrase it if it helps.</p> <p>2 Did you separately assess the Berge --</p> <p>3 excuse me -- the power calculation in either the Narod</p> <p>4 article or the Berge article?</p> <p>5 A. If I may go back to my report for just a</p> <p>6 moment.</p> <p>7 Q. Sure.</p> <p>8 A. I think that this statement that I have</p> <p>9 here -- I'm -- I think my intent in my report was</p> <p>10 indicating that the lack of statistical significance</p> <p>11 in the individual studies was a power concern.</p> <p>12 Berge was talking about the statistical</p> <p>13 power for the combined studies. So I think that there</p> <p>14 is some distinction there between what I'm referring</p> <p>15 to individual studies versus what Berge is describing</p> <p>16 as the power of the combined analysis.</p> <p>17 Q. Well, Berge is saying that the low power of</p> <p>18 cohort studies cannot be invoked as an explanation for</p> <p>19 the heterogeneity of results.</p> <p>20 Do you agree or disagree with that</p> <p>21 statement?</p> <p>22 A. When they are combining them, I -- I don't</p> <p>23 disagree with that. I think there are other reasons</p> <p>24 that can explain the heterogeneity.</p> <p>25 Q. On page 25, we've touched upon this already,</p>	<p>1 follow-up; correct?</p> <p>2 A. I believe so.</p> <p>3 Q. And we know that the Penninkilampi paper did</p> <p>4 not include the additional 10 years of follow-up as</p> <p>5 reflected by the Gates 2010 paper; correct?</p> <p>6 A. Yes. We have already -- you've already asked</p> <p>7 and I've already answered that.</p> <p>8 Q. And then the next one you discuss is the WHI</p> <p>9 study where you are reporting Penninkilampi's</p> <p>10 reporting of 12.4 years of follow-up; correct?</p> <p>11 A. That is correct.</p> <p>12 Q. And do you know that the follow-up period in</p> <p>13 the WHI -- do you know that the WHI asked about</p> <p>14 duration of talc use?</p> <p>15 A. May I go back to that study?</p> <p>16 Q. Sure.</p> <p>17 A. Do you --</p> <p>18 Q. It's 25.</p> <p>19 A. Yes, they describe in their exposure</p> <p>20 assessment, that they did ask about duration of use</p> <p>21 using five categories from less than a year all the</p> <p>22 way up to 20 or more years.</p> <p>23 Q. And so we know that they -- they followed the</p> <p>24 study participants for, according to Penninkilampi,</p> <p>25 12.4 years. But, in addition to that, they also asked</p>

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<p>1 about the -- study participants about their prior 2 duration of usage; correct? 3 A. They asked about that, but I think that one 4 has to consider some of the caveats that go along with 5 that. These -- may I continue? 6 These women, they report that they were, on 7 average, 63 years of age when they -- at baseline, so 8 at the start of enrollment in the cohort. So they 9 were asking them to recall an exposure that went back, 10 for many women, that probably started in their teens 11 or twenties. So there was certainly the possibilities 12 of some inaccurate recall because they were asking 13 them to recall an exposure that went back quite a few 14 years. 15 Another consideration with this study is 16 they excluded roughly -- let's see -- the cohort 17 was -- they started off with 90-some-thousand women in 18 the cohort, and they excluded any history of any women 19 with cancer at baseline, which is appropriate to do, 20 but the potential concern about that is, if there were 21 talc users who had developed ovarian -- or had 22 developed ovarian cancer before the follow-up began, 23 that would never be captured. 24 MR. JAMES: Okay. Dr. Moorman, just 25 very respectfully, I'm going to have to object to the</p>	<p>1 excuse me -- page 26, you discuss updating exposure 2 information in the cohort studies. 3 A. Yes. 4 Q. Do you have any basis to dispute the accuracy 5 of the reported talc use at the time it was initially 6 ascertained in the cohort studies? 7 A. The accuracy of the reported talc use at the 8 time that they started follow-up in the cohorts. 9 Q. Correct. 10 A. I believe that, when you are asking people to 11 recall exposures that occurred over a long period of 12 time, there will be some inadvertent inaccuracies. 13 Q. And are you saying with respect to questions 14 about duration? 15 A. It could be with ever use or with duration. 16 Some women who used it might have forgotten and never 17 reported it. So that's just kind of an inherent 18 problem anytime you ask someone to recall exposures, 19 particularly if they might have occurred decades ago. 20 Q. Is that true for the case-control studies as 21 well? 22 A. Yes. In my report, I indicate that -- I make 23 the distinction between recall bias and inaccurate 24 recall and indicate that inaccurate recall -- 25 specifically on page 21, make the distinction between</p>
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<p>1 nonresponsive portion of the answer. 2 BY MR. JAMES: 3 Q. So the question that I asked is not the 4 question that you ended up answering. 5 A. I did answer your question, I believe. 6 Q. Okay. I didn't ask you for your critiques of 7 the WHI. I asked you about the follow-up issue. 8 Okay? Do we need to look at the question again? 9 I asked -- my question is: 10 "Question: But in addition to that, 11 they also asked about -- the study 12 participants about their prior 13 duration of usage; correct?" 14 A. And I answered it but thought that there were 15 important relevant considerations. 16 MR. JAMES: Can we go off the record 17 for a second -- 18 MS. PARFITT: Yes. 19 MR. JAMES: -- please? 20 THE VIDEOGRAPHER: Off record at 3:29. 21 (Discussion off the record.) 22 THE VIDEOGRAPHER: Back on record at 23 3:31 p.m. 24 BY MR. JAMES: 25 Q. On page 25 of your report, Dr. Moorman --</p>	<p>1 recall bias and inaccurate recall that is difficult -- 2 inaccurate recall and exposure that is difficult to 3 remember with precision. 4 And that's an issue with any type of study 5 when you're asking people to recall past exposures. 6 Q. And transitioning to the topic that you 7 brought up, which is the recall bias. We can stay on 8 page 216 your report. 9 A. Yes. 10 Q. And there, you address -- at the bottom 11 paragraph, you say that (as read): 12 "Recall bias, which theoretically 13 could result in the bias estimate 14 of the relative risk, must be 15 considered." 16 Do you see where I am? 17 A. I do. 18 Q. And you cite three situations where recall 19 bias would be a "particular threat" to a study's 20 validity; right? 21 A. Yes. 22 Q. And with -- let's walk through those three 23 together. 24 The first is -- the first threat that you 25 identify is "if the exposure of interest is one that</p>

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<p>1 could be considered sensitive"; right?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And then you address that reason in</p> <p>4 turn on the next page, on page 22 of your report?</p> <p>5 A. Yes.</p> <p>6 Q. And you state there that (as read):</p> <p>7 "In regard to the situation,</p> <p>8 genital talc use would 'not be</p> <p>9 considered a particularly</p> <p>10 sensitive topic.'"</p> <p>11 Right?</p> <p>12 A. That's what I state in my report, yes.</p> <p>13 Q. Okay. And what basis do you have for that</p> <p>14 statement? Do you cite to anything? Have you</p> <p>15 conducted any studies to support that statement? What</p> <p>16 scientific basis do you have for that statement?</p> <p>17 A. This is based on my professional judgment,</p> <p>18 based on years and years of doing studies where we</p> <p>19 collect data, getting feedback from interviewers. In</p> <p>20 our studies, we ask about a lot of personal things,</p> <p>21 you know, their menstrual history, their contraceptive</p> <p>22 history, those kind of things.</p> <p>23 And I have never gotten the impression that</p> <p>24 these were things that women considered sensitive and</p> <p>25 did not want to reveal, whereas when you get into</p>	<p>1 them, or any reason why a woman, if she's telling you</p> <p>2 her whole pregnancy and menstrual history, why she</p> <p>3 would feel embarrassed about her use of genital talc.</p> <p>4 Q. And do you have any empirical data to support</p> <p>5 that opinion?</p> <p>6 A. I am unaware of any empirical data that</p> <p>7 specifically addresses that.</p> <p>8 Q. Okay. The second situation you identify on</p> <p>9 page 21 and then discuss on page 22 is if -- is if the</p> <p>10 study hypotheses are known to the study subjects or</p> <p>11 interviewers.</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And your analysis is on page 22.</p> <p>15 What did you do to evaluate this factor?</p> <p>16 A. Whether the study hypotheses are known to the</p> <p>17 study subjects or interviewers?</p> <p>18 Q. Correct. With respect to the talc ovarian</p> <p>19 cancer literature.</p> <p>20 A. Okay. Again, this is based on my experience</p> <p>21 in having done epidemiologic studies for many years.</p> <p>22 As I state here, it's standard practice in</p> <p>23 epidemiologic research where we're not discussing the</p> <p>24 hypotheses with the interviewers. We're asking a lot</p> <p>25 of questions. Some thought to increase risk; some</p>
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<p>1 other topics, say -- like, I give the example of</p> <p>2 induced abortion, that, I have heard from some of our</p> <p>3 interviewers, that sometimes that evokes strong</p> <p>4 emotions in the women.</p> <p>5 And so I think that, you know, there are</p> <p>6 some exposures that are sensitive, as I describe, that</p> <p>7 women might be hesitant to report. And I contrast</p> <p>8 that with things that are personal but not</p> <p>9 particularly sensitive.</p> <p>10 When a woman has agreed to be in a study,</p> <p>11 she knows that we're going to be asking some of these</p> <p>12 questions. And I have never heard any comments from</p> <p>13 any of the interviewers in the many studies I've done</p> <p>14 that this was a question that women felt uncomfortable</p> <p>15 with.</p> <p>16 Q. Do you acknowledge the possibility that a</p> <p>17 person's use of a cosmetic talcum powder in their</p> <p>18 genital region could be viewed by some as a sensitive</p> <p>19 topic?</p> <p>20 A. I -- again, I -- I kind of make the</p> <p>21 distinction between something that is personal -- and</p> <p>22 we ask them a lot of personal questions, but it's --</p> <p>23 I don't see any aspect of that that would seem</p> <p>24 particularly sensitive, why someone might be</p> <p>25 embarrassed or feel that someone was going to judge</p>	<p>1 thought to decrease risk. It's standard that you</p> <p>2 would not really discuss the hypotheses with the</p> <p>3 interviewers.</p> <p>4 And, similarly, when we invite or ask women</p> <p>5 to be in our studies, we will tell them that, you</p> <p>6 know, it is a study of ovarian cancer, but we're not</p> <p>7 telling them which factors we think might be</p> <p>8 associated with increased risk and which ones might be</p> <p>9 associated with decreased risk.</p> <p>10 Q. To support this statement, did you conduct</p> <p>11 any post-interview interviews?</p> <p>12 A. Can you restate that? Tell me -- I'm not</p> <p>13 sure what you're asking.</p> <p>14 Q. So to determine if study hypotheses were</p> <p>15 known to the study subjects at the time that they were</p> <p>16 asked the questions, there would be methods or ways to</p> <p>17 which you could find that out; correct?</p> <p>18 A. We -- I'm thinking about it. I have never</p> <p>19 known that to be -- I've never known a study that has</p> <p>20 done that.</p> <p>21 In one breast cancer study, at the end of</p> <p>22 the interview, we asked the women if they had any</p> <p>23 ideas about what caused breast cancer. And, you know,</p> <p>24 we thought it might maybe raise some new ideas, but we</p> <p>25 found that it was largely -- we didn't see anything</p>

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<p>1 that was usable. I think that the most common</p> <p>2 response was that women thought it was stress. So --</p> <p>3 Q. But you don't have any evidence of anything</p> <p>4 similar being done in the talc ovarian cancer</p> <p>5 literature; correct?</p> <p>6 A. Not to my knowledge.</p> <p>7 Q. At the bottom of page 22, and then carrying</p> <p>8 over through 23, you cite to the Lanza study; correct?</p> <p>9 A. That's correct.</p> <p>10 Q. And you cite Lanza for the proposition</p> <p>11 that -- to provide "further evidence that recall bias</p> <p>12 in case-control studies does not inevitably lead to an</p> <p>13 overestimate."</p> <p>14 Do you see where I was reading? It's at the</p> <p>15 bottom of 22.</p> <p>16 A. Yes. Yes, I see where you're reading.</p> <p>17 Q. Lanza did not pertain to talc and ovarian</p> <p>18 cancer; correct?</p> <p>19 A. As I state in my report, yes. It's looking</p> <p>20 at a variety of meta-analyses that looked at both</p> <p>21 case-control studies and cohort studies. And the</p> <p>22 point of that paper was to determine if recall bias</p> <p>23 seemed to lead to a consistently increased risk. And</p> <p>24 their conclusion, as I state in here, there's no</p> <p>25 significant difference in the effect estimates between</p>	<p>1 are that the estimates did not differ between</p> <p>2 case-control and prospective or retrospective cohort</p> <p>3 studies; correct?</p> <p>4 A. Where are you reading, please?</p> <p>5 Q. I'm in the "Results" section.</p> <p>6 A. Okay. Yes.</p> <p>7 Q. And then they say, "Heterogeneity was also</p> <p>8 low," below that; right?</p> <p>9 A. Yes.</p> <p>10 Q. Again, if I'm understanding this paper</p> <p>11 correctly, the situation for talc and ovarian cancer</p> <p>12 is completely different, isn't it? Where we do have</p> <p>13 heterogeneity between the prospective studies and the</p> <p>14 retrospective case-control studies; right?</p> <p>15 MS. PARFITT: Objection. Form.</p> <p>16 THE WITNESS: We have one example in</p> <p>17 the talc and the -- and the ovarian cancer -- in the</p> <p>18 meta-analyses, they did note some heterogeneity</p> <p>19 between the cohort studies and the case-control</p> <p>20 studies.</p> <p>21 I think that the point that I was trying to</p> <p>22 get with that is in the observational studies, there's</p> <p>23 always concern, as several of these people have -- as</p> <p>24 several of the meta-analyses and other papers have</p> <p>25 reported, that the stronger association due to --</p>
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<p>1 the case-control and cohort studies, suggesting that</p> <p>2 the study design didn't have an important impact on</p> <p>3 the conclusions of the meta-analyses.</p> <p>4 MR. JAMES: Okay. I marked Lanza as</p> <p>5 Exhibit 27. I'll hand you two copies.</p> <p>6 (Exhibit No. 27 was marked for identification.)</p> <p>7 BY MR. JAMES:</p> <p>8 Q. And so Lanza concerns therapeutic</p> <p>9 interventions; correct?</p> <p>10 A. Yes.</p> <p>11 Q. And isn't -- and correct me if I'm wrong</p> <p>12 here, but looking at Lanza, isn't what Lanza doing is</p> <p>13 they're comparing the odds ratios reached in both the</p> <p>14 case-control studies and in the prospective studies on</p> <p>15 a completely different body of literature; right?</p> <p>16 A. It is not dealing with talc and ovarian</p> <p>17 cancer, if that is your question.</p> <p>18 Q. And they're looking at whether the results of</p> <p>19 the case-control studies on that separate body of</p> <p>20 literature and the results of the prospective cohort</p> <p>21 studies on that separate body of literature reached</p> <p>22 different results; right?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And so the author's conclusions in the</p> <p>25 abstract here are -- which you note in your report --</p>	<p>1 among the case-control studies was due to some kind of</p> <p>2 recall bias.</p> <p>3 So the point is, if it was recall bias, you</p> <p>4 would expect to see that case-control studies always</p> <p>5 had higher estimates than the cohort studies; and this</p> <p>6 study is making the point that in this wide variety of</p> <p>7 interventions that they looked at, that doesn't seem</p> <p>8 to be the case at all. Okay.</p> <p>9 BY MR. JAMES:</p> <p>10 Q. So, again, this study is saying, "Look, the</p> <p>11 results of case-control studies and the results of</p> <p>12 prospective cohort studies on these therapeutic</p> <p>13 interventions are similar, same ballpark, and so thus,</p> <p>14 we can conclude that recall bias in this body of</p> <p>15 literature must not be a big deal."</p> <p>16 Is that a layman's fair way to describe the</p> <p>17 results of this paper?</p> <p>18 MS. PARFITT: Objection. Form.</p> <p>19 THE WITNESS: Yeah. I -- I mean,</p> <p>20 I think that it's one part of the -- I think that,</p> <p>21 overall, that's a pretty fair summary of the point</p> <p>22 that this paper is making. So...</p> <p>23 BY MR. JAMES:</p> <p>24 Q. And if you acknowledge that in the talc</p> <p>25 ovarian cancer literature, there is a disparity</p>

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<p style="text-align: right;">Page 230</p> <p>1 between the retrospective case-control studies and the 2 prospective cohort studies, then Lanza isn't really 3 applicable at all, is it? 4 MS. PARFITT: Objection. 5 THE WITNESS: It is -- I think that it 6 is very applicable because it's trying to get at the 7 recall -- is recall bias -- is that a problem in 8 case-control studies that is going to inevitably lead 9 to higher risk estimates than what you would get in 10 cohort studies? 11 And as we have seen in these articles, we 12 see recall bias is frequently cited as a potential 13 reason that we saw stronger associations in 14 case-control studies than in cohort studies. 15 And I think this paper is really pointing 16 out that that's not inevitable, that you're always 17 going to have higher estimates with case-control 18 studies than cohort studies. 19 Specifically in relation to the 20 heterogeneity between the cohort studies and the 21 case-control studies in talc, I think that we have to 22 consider other biases that may be operating. 23 BY MR. JAMES: 24 Q. I mean, the justification for the Lanza 25 conclusions is that the results in the two study</p>	<p style="text-align: right;">Page 232</p> <p>1 Q. If you're looking at Lanza objectively, 2 doesn't it say exactly the opposite of what you're 3 saying here, Doctor? 4 I mean, again, the justification for Lanza 5 is the results are the same, and so recall bias isn't 6 a problem. But that justification doesn't exist in 7 the world of talc ovarian cancer. 8 That will be my last question on that. 9 A. No. I think that this addresses the recall 10 bias in the -- you know, I acknowledge it doesn't 11 directly address talc and ovarian cancer in this 12 paper; but it does address this -- this commonly-cited 13 thing that, you know, recall bias in case-control 14 studies could lead to higher risk estimates. And it's 15 saying that's not necessarily the case always. 16 Q. I promised that was my last question -- 17 A. Okay. 18 Q. -- so we'll move on. 19 The third factor that you discuss as a 20 particular threat for recall bias is if there is 21 considerable media attention. 22 Do you see where I've returned back to on 23 page 22? 24 21 is where you -- 21 through 22 is where 25 you lay out the three reasons. At the top of 22, you</p>
<p style="text-align: right;">Page 231</p> <p>1 designs are pretty much the same. So these two study 2 designs didn't reach different results. And so in 3 this body of literature, we don't really need to be 4 worried about recall bias. Recall bias was not 5 operating to create a disparity of results in this 6 body of literature. 7 But, in contrast, in the talc ovarian cancer 8 world, there is a disparity in the results by study 9 design; right? 10 A. We've already acknowledged there is some 11 heterogeneity in results. Is it due to recall bias? 12 Is it -- do we have to assume that recall bias is in 13 play here and that explains the higher -- or the 14 stronger associations generally reported in the 15 case-control studies. 16 And this article is addressing one -- one 17 potential bias, the recall bias. And I don't -- 18 I think that it provides support that we cannot just 19 do a knee-jerk reaction of "case-control studies, they 20 have the potential for recall bias, that leads to 21 higher estimates, and therefore, these studies are 22 biased." 23 There are other biases in play in the cohort 24 studies that I think are very plausible explanations 25 for why there might be some differences.</p>	<p style="text-align: right;">Page 233</p> <p>1 say "considerable media attention." 2 A. Yes. 3 Q. And then you evaluate the media attention 4 factor on the following page; right? 5 A. On page 23, yes. 6 Q. On 23, you say that, for the media attention 7 concern, you say in the middle of the first full 8 paragraph (as read): 9 "The concern is not relevant to 10 the vast majority of the studies 11 as virtually all the data 12 collection in the epidemiologic 13 studies of talc and ovarian cancer 14 occurred prior to such 15 litigation." 16 Do you see that? 17 A. Yes, I do. 18 Q. And you agree that media attention is not 19 limited to litigation; correct? 20 A. Yes. 21 Q. Did you undertake any effort to analyze the 22 extent of publicity or media attention to the talc 23 ovarian cancer issue prior to 2014? 24 A. I did not do any specific analysis of that. 25 I personally was unaware of any media attention on</p>

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<p>1 this topic prior to the litigation. 2 Q. Then I believe on page 23, you go on to 3 discuss the Schildkraut 2016 paper; correct? 4 A. Yes. 5 Q. Okay. And if we can pull that back out. It 6 is the exhibit -- did I mark it? 7 MS. PARFITT: I don't think so. 8 MR. JAMES: Okay. I'll mark it as the 9 next one, so you don't have to fish for it here. It's 10 Exhibit 28. 11 (Exhibit No. 28 was marked for identification.) 12 MR. JAMES: Which is the Schildkraut 13 2016 paper. I'll hand you two copies. 14 BY MR. JAMES: 15 Q. And so we touched upon this a bit earlier, 16 Dr. Moorman, where we talked about the phraseology 17 where you say the association was "attenuated but not 18 eliminated." 19 Do you recall that exchange we had earlier? 20 THE WITNESS: Yes, I do. 21 BY MR. JAMES: 22 Q. Okay. And in this 2016 paper, again, you, 23 among the authors, compared the odds ratios for talc 24 and ovarian cancer for participants before 2014 and 25 for participants after 2014; correct?</p>	<p>1 Q. And you -- I believe this table reflects -- 2 though I'm still looking for it, and maybe you can 3 help me with it -- but the data in this table reflects 4 that pre-2014 interviewees reported talc usage at the 5 rate of 36 percent, and post-2014 interviewees 6 reported rates -- excuse me, reported usage at the 7 rate of 51 percent. 8 A. Yes, I see that in the table. 9 Q. And so that's a significant disparity in 10 reported usage rates; would you agree with that? 11 MS. PARFITT: Objection. Form. 12 THE WITNESS: Clearly, it is what it 13 is. It's 36 percent as -- versus 51 percent. Okay. 14 BY MR. JAMES: 15 Q. And so we have your paper here showing that 16 before 2014, before the onset of the litigation, you 17 had study participants reporting talc usage at a lower 18 rate; right? 19 A. Than -- yes. 20 Q. And if you isolated the association analysis 21 to those -- to that group, you also have a 22 non-statistically significant association; correct? 23 A. And again, when you stratify -- we've already 24 covered that. I acknowledge that prior to 2014, it 25 was not statistically significant. We also indicated</p>
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<p>1 A. Correct. 2 Q. And if we look at page 1414 -- I'm looking 3 for my place here. 4 If you look at Table 2, Dr. Moorman, you see 5 there where you have broken out the data on interview 6 date after 2014; right? 7 A. Yes. 8 Q. And then above that is the interview date 9 before 2014; correct? 10 A. Yes. 11 Q. And we see that the odds ratio here for 12 interview date after 2014 is 2.91; correct? 13 A. That is correct. 14 Q. That's well in excess of any odds ratio 15 reported in any of the meta-analyses; correct? 16 A. For the overall summary odds ratio, yes. 17 Q. And before 2014, we see that the odds ratio 18 is a 1.19 that is not statistically significant, which 19 is what we discussed earlier; correct? 20 A. Yes, we discussed that earlier. 21 Q. And you also report in this article a 22 distinction between the pre-2014 interviewees and the 23 post-2014 interviewees based upon their reported talc 24 usage; right? 25 A. Yes.</p>	<p>1 certainly in the range of what many other studies have 2 seen. But when you stratify like that, you are 3 getting into smaller sample sizes. So there's 4 statistical significance that -- the fact that it's no 5 longer statistically significant is not all that 6 surprising. 7 Q. Have you seen the Trabert editorial that 8 followed the publication of the Schildkraut article? 9 A. I'm sure that I have read it at some point, 10 but -- 11 Q. Okay. I'm going to -- I'm sorry. 12 A. -- please, let's -- I haven't looked at it in 13 quite some time. 14 Q. So I'm going to mark as Exhibit 29 an 15 editorial by Britton Trabert entitled "Body Powder and 16 Ovarian Cancer Risk -- What is the Role of Recall 17 Bias?" 18 I'll hand you two copies. 19 (Exhibit No. 29 was marked for identification.) 20 BY MR. JAMES: 21 Q. Dr. Moorman, does this editorial look 22 familiar to you? Have you seen it before? 23 A. Yes, I have seen it before. 24 Q. Have you ever spoken with or communicated 25 with Britton Trabert about this editorial?</p>

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<p>1 A. No, I have not.</p> <p>2 Q. And you see that in the right-hand column,</p> <p>3 about midway down, Dr. Trabert refers to the data</p> <p>4 points that we were just discussing; correct?</p> <p>5 A. Yes.</p> <p>6 Q. And if you look to the second page of the</p> <p>7 editorial, Trabert reports, at the last paragraph of</p> <p>8 the article (as read):</p> <p>9 "The current study highlights the</p> <p>10 concern over recall bias in</p> <p>11 case-control studies, particularly</p> <p>12 once an exposure becomes the</p> <p>13 subject of considerable media</p> <p>14 coverage."</p> <p>15 Do you see where I was reading that?</p> <p>16 A. Yes, I do.</p> <p>17 Q. Do you agree with Dr. Trabert's concerns</p> <p>18 about media coverage impacting the results of the</p> <p>19 Schildkraut study?</p> <p>20 A. I -- I think that the investigators on our</p> <p>21 study, they had that concern. That's why we did those</p> <p>22 analyses. So...</p> <p>23 Q. So do you acknowledge the possibility that</p> <p>24 the results of the 2016 study may reflect recall bias</p> <p>25 in the study?</p>	<p>1 possibility of recall bias, but I think that we looked</p> <p>2 at the other side of the coin as well.</p> <p>3 Q. And can you tell me where you're reading that</p> <p>4 sentence from, Dr. Moorman?</p> <p>5 A. Let's see. The -- it is on page 1416, the</p> <p>6 right-hand column, and it's about -- probably about</p> <p>7 eight or nine lines down.</p> <p>8 So I think that this sentence -- or this</p> <p>9 whole paragraph gives a pretty balanced assessment of</p> <p>10 the data, that we thoughtfully considered the issue of</p> <p>11 recall bias, but we also considered that maybe the</p> <p>12 greater publicity led to -- was kind of a memory</p> <p>13 trigger that led to more accurate recall.</p> <p>14 Q. And in your report, do you include a caution</p> <p>15 on the Schildkraut 2016 study about the potential for</p> <p>16 recall bias based upon the 2014 pre- and post-data?</p> <p>17 A. I -- let's see. We have discussed that</p> <p>18 section of the report a couple of times already. And</p> <p>19 I state that there is the possibility that recall bias</p> <p>20 could have led to the higher odds ratios when</p> <p>21 including women interviewed during the time when there</p> <p>22 was more media attention focused on this exposure.</p> <p>23 Q. And you're at page 23; right?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. And then you conclude the middle</p>
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<p>1 A. In this discussion -- if I may take just a</p> <p>2 moment to --</p> <p>3 Q. Certainly.</p> <p>4 A. Okay. You know, I think that</p> <p>5 Dr. Schildkraut, who did the major writing of this</p> <p>6 article -- and I think all of the coauthors were in</p> <p>7 agreement -- that we were concerned about the recall</p> <p>8 bias. As I said, that was some of the reason for</p> <p>9 doing those analyses.</p> <p>10 I think that it's also important to point</p> <p>11 out here the other possibility. There may have been</p> <p>12 some recall bias. But she also makes the statement</p> <p>13 that (as read):</p> <p>14 "It is possible that the lawsuit</p> <p>15 sharpened memories of body powder</p> <p>16 use and improved the accuracy of</p> <p>17 reported use for both cases and</p> <p>18 controls interviewed in 2014 or</p> <p>19 later."</p> <p>20 I think that that goes to say that anytime</p> <p>21 someone -- you know, there's some memory trigger, it</p> <p>22 could have made actually more accurate recall.</p> <p>23 So we --</p> <p>24 Q. And Dr. --</p> <p>25 A. I'm sorry. So we acknowledge both the</p>	<p>1 paragraph with the statement that -- the "attenuated</p> <p>2 but not eliminated" statement. But I'm not going to</p> <p>3 ask about that again. But you go on in that sentence</p> <p>4 to say (as read):</p> <p>5 "The association is not due</p> <p>6 entirely to recall bias."</p> <p>7 Do you see that phrasing that I just read?</p> <p>8 A. Yes.</p> <p>9 Q. So are you conveying in that wording that you</p> <p>10 think some portion of the odds ratio that you are</p> <p>11 seeing in these case-control studies that you're</p> <p>12 relying on or the meta-analyses that you're relying</p> <p>13 on, that some portion of that odds ratio is</p> <p>14 attributable to recall bias?</p> <p>15 MS. PARFITT: Objection.</p> <p>16 THE WITNESS: I think that probably</p> <p>17 every meta-analysis published, probably every</p> <p>18 case-control study that was published, we acknowledge</p> <p>19 this as a -- recall bias is a potential bias. But</p> <p>20 I think that we went on to give evidence --</p> <p>21 I explained why I did not think that it was a complete</p> <p>22 explanation.</p> <p>23 Can we completely rule out any possibility</p> <p>24 of recall bias? I don't know that we can do it. But</p> <p>25 I think that as -- for some of the reasons</p>

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<p>1 I articulated.</p> <p>2 I know that Dan Cramer in his 2016 paper</p> <p>3 also went into great detail considering the issue of</p> <p>4 recall bias. And I don't think that we can attribute</p> <p>5 this association to recall bias.</p> <p>6 BY MR. JAMES:</p> <p>7 Q. Can you cite to any publication that has</p> <p>8 analyzed the literature and ruled out recall bias --</p> <p>9 MS. PARFITT: Objection.</p> <p>10 BY MR. JAMES:</p> <p>11 Q. -- as a method -- as a basis for the elevated</p> <p>12 odds ratio of the 1.2 to 1.3 that you're citing in</p> <p>13 your report?</p> <p>14 MS. PARFITT: Objection.</p> <p>15 THE WITNESS: Okay. I went back to the</p> <p>16 Dan Cramer article, and I'm hoping that I'm recalling</p> <p>17 that particular article, the date of it, accurately.</p> <p>18 But he did analyze the data and the degree of</p> <p>19 misclassification that would have had to occur for</p> <p>20 recall bias to account for this association. He gave</p> <p>21 other reasons for why it seemed unlikely that recall</p> <p>22 bias would account for this association.</p> <p>23 So I think he did a pretty thorough</p> <p>24 analysis -- a thoughtful analysis of it.</p> <p>25</p>	<p>1 Q. Okay. Dr. Moorman, on page 11 of your</p> <p>2 report, you talk about -- this is where you begin your</p> <p>3 analysis of the Bradford Hill factors.</p> <p>4 A. Yes.</p> <p>5 Q. And are you there with me?</p> <p>6 A. Yes, I am.</p> <p>7 Q. Okay. You say, in page 11 -- you have a</p> <p>8 section titled "Strength and consistency of the</p> <p>9 association"; correct?</p> <p>10 A. Correct.</p> <p>11 Q. You say in the first sentence that strength</p> <p>12 and consistency are "deeply intertwined." Correct?</p> <p>13 A. Yes.</p> <p>14 Q. Can you cite to any publication where you</p> <p>15 have combined the analysis of strength and consistency</p> <p>16 before?</p> <p>17 A. I -- I can't cite any publication that</p> <p>18 specifically addresses that, no.</p> <p>19 Q. Can you cite any published authority that</p> <p>20 states these two Bradford Hill criteria are deeply</p> <p>21 intertwined?</p> <p>22 A. I -- I think that as I was -- I cannot cite a</p> <p>23 published authority.</p> <p>24 I think that, again, this is based on when</p> <p>25 I was looking at these and how I was weighting these</p>
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<p>1 BY MR. JAMES:</p> <p>2 Q. Can you cite any other publications other</p> <p>3 than the Cramer 2016 paper, sitting here today, that</p> <p>4 have addressed recall bias in the fashion that you</p> <p>5 just described?</p> <p>6 A. The Cramer article is the one that I -- that</p> <p>7 comes to mind as the one that addressed it most</p> <p>8 thoroughly.</p> <p>9 Q. Have you ever published the three factors</p> <p>10 that you have addressed with regard to recall bias?</p> <p>11 A. The three factors are --</p> <p>12 Q. Sure. So --</p> <p>13 A. Okay.</p> <p>14 Q. Within your report, you -- we just walked</p> <p>15 through the three factors that you've considered, the</p> <p>16 three factors that you deemed to be a particular</p> <p>17 threat to case-control studies for recall bias;</p> <p>18 correct? We just walked through those three?</p> <p>19 A. Yes.</p> <p>20 Q. Have you ever published those three in any</p> <p>21 article or journal or anything else?</p> <p>22 A. I have not published that. That is just</p> <p>23 based on my general epidemiologic knowledge from doing</p> <p>24 this type of research and teaching in this field for</p> <p>25 the last couple of decades.</p>	<p>1 considerations.</p> <p>2 Q. Do you agree that strength is an important</p> <p>3 criteria in and of itself?</p> <p>4 A. I think that the strength of the association</p> <p>5 is an important criteria, but I think that we also</p> <p>6 have to bear in mind that as -- that there are many</p> <p>7 well-established causal associations that are</p> <p>8 certainly not in the order of magnitude of what we</p> <p>9 see, for example, with smoking and lung cancer.</p> <p>10 Q. Do you think the criteria of strength is met</p> <p>11 with the talc and ovarian cancer literature?</p> <p>12 A. When -- as I go through my report, I give</p> <p>13 numerous examples of well-accepted causal associations</p> <p>14 that are of a similar magnitude as what we see with</p> <p>15 talc and ovarian cancer, and so I think that the data</p> <p>16 are strong enough.</p> <p>17 Q. And I think that I'm going to ask my question</p> <p>18 again.</p> <p>19 A. Okay.</p> <p>20 Q. Do you think that the criteria of strength is</p> <p>21 met with the talc and ovarian cancer literature?</p> <p>22 A. Okay --</p> <p>23 MS. PARFITT: Objection. Asked and</p> <p>24 answered.</p> <p>25 Try again, Dr. Moorman.</p>

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<p>1 THE WITNESS: Okay. So, once again, 2 I -- we have to use -- we have to be careful of -- 3 Dr. Hill did not refer to these as "criteria," but 4 guidelines or viewpoints I think was the terminology 5 he used. And I do think that the criteria of strength 6 has been met. 7 BY MR. JAMES: 8 Q. Can you cite to a single study in the talc 9 ovarian cancer literature that refers to the 10 association as a strong association? 11 A. I -- I cannot, off the top of my head, think 12 of anyone that refers to it as a strong association. 13 I do, once again, want to say that we see evidence of 14 causal associations of similar magnitude; so I think 15 that it is strong enough to be a causal association. 16 Q. Do you understand that a number of the papers 17 that you have cited in your reference list or 18 materials-considered list refer to the association as 19 weak? 20 MS. PARFITT: Objection. 21 THE WITNESS: Which papers are you 22 referring to specifically? 23 BY MR. JAMES: 24 Q. If an author in the talc ovarian cancer 25 literature has referred to the association as a weak</p>	<p>1 MR. JAMES: It hasn't been answered. 2 MS. PARFITT: It's been asked. 3 THE WITNESS: I don't think that we 4 have any actual definition of what is modest. I think 5 that the association is what it is, a 25 to 30 percent 6 increased risk. 7 BY MR. JAMES: 8 Q. As an epidemiologist, you're not capable of 9 discerning whether an association is modest or not 10 modest? 11 MS. PARFITT: Objection. 12 THE WITNESS: As I have said before, 13 I don't think there is any clear definition of that 14 adjective. 15 BY MR. JAMES: 16 Q. Is there a definition in the epidemiologic 17 community of a weak association? Are you able to 18 understand what that would mean in the epidemiologic 19 community? 20 A. Once again, there is no -- to my knowledge, 21 there is nothing that would say, you know, an odds 22 ratio in this range is weak, this is modest, this is 23 moderate, this is strong. 24 And, again, going back to Bradford Hill, he 25 certainly emphasizes that there are some associations</p>
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<p>1 association, would you agree or disagree with that 2 characterization? 3 MS. PARFITT: Object to form. 4 THE WITNESS: I would disagree with 5 the -- I would disagree with that. 6 BY MR. JAMES: 7 Q. If an author or authors in the talc ovarian 8 cancer literature have referred to the association as 9 modest, would you agree or disagree with that? 10 A. Once again, I think that many of the risk 11 factors that we are considering are not going to be 12 the odds ratios of 10 or greater that we saw with 13 this. 14 And when you read the papers written by 15 Dr. -- by Bradford Hill, he certainly makes the point 16 that some weaker associations can certainly be real. 17 Q. So is this a weaker association? 18 A. Weaker is in comparison to what? It's not -- 19 it's weaker than smoking and lung cancer. It is -- 20 I keep making the point that it -- we fully 21 acknowledge that it is not a tenfold increased risk. 22 It's a 25 to 30 percent increased risk. 23 Q. Would you call the association modest? 24 MS. PARFITT: Objection. Asked and 25 answered.</p>	<p>1 that are not in the magnitude of smoking and lung 2 cancer, but they are certainly real. 3 Q. And I think you're conflating -- or you're 4 misunderstanding my question, because you're answering 5 the question about whether the association is real or 6 not real, and my question for you is whether the 7 association is weak, modest, or strong. 8 How would you characterize it? 9 A. And I would -- as I have said, there is no 10 absolute terminology that would say what is a weak 11 association, what is modest, and what is strong. So 12 I think that it is more accurate just to describe it 13 as it is, a 25 to 30 percent increased risk of ovarian 14 cancer. 15 Q. Well, in assessing the Bradford Hill factors 16 or considerations or criteria -- in assessing that and 17 determining whether the association is strong or not 18 strong, as an epidemiologist, don't you need to be 19 capable of determining whether the association is 20 strong or not strong? 21 A. Once again, it is an adjective that is not 22 well defined. And -- 23 Q. And do you -- I'm sorry. 24 A. I -- I -- I keep going back to I think that 25 the association that we see is what it is, a 25 to</p>

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<p>1 30 percent increased risk. It is consistent with 2 other factors that we consider causal associations. 3 They have a similar strength of association. 4 Q. And I do -- I do intend to go to that very 5 next topic next -- 6 A. Okay. 7 Q. -- but in assessing strength, what I'm asking 8 is whether, in all of the papers that you've cited, 9 when the epidemiologists that you've cited refer to 10 the association as weak or modest or small, is that 11 terminology that you can accept, or is that 12 terminology that you reject? 13 A. I say that it is terminology that is 14 imprecise. What one would consider modest, someone 15 else might consider moderate. It's imprecise 16 terminology. 17 Q. And certainly in the epidemiology world, if 18 you have a small or modest or weak association, what 19 you're saying is that that doesn't bar a causal 20 conclusion. But wouldn't you agree with me that if 21 the association is small or modest or weak, it makes 22 the other considerations more important? 23 MS. PARFITT: Objection. 24 THE WITNESS: I think that all of the 25 considerations are important. It's --</p>	<p>1 A. Yes. 2 Q. And these associations that you've listed, 3 you have concluded are generally accepted to be 4 causal; correct? 5 A. I think so, yes. 6 Q. And below that, you state that the IARC has 7 reached a causal conclusion with respect to each of 8 these associations; is that right? 9 A. Yes, that is what I state. 10 Q. And so to state that, are you saying that all 11 five of these exposures and associations have been 12 classified by IARC as Category 1? 13 A. I don't recall if -- I don't recall the 14 classifications, specifically, for all of these. 15 Q. Well, to say that the IARC has made a causal 16 judgment on these associations, you are necessarily 17 saying that they have classified these associations as 18 Category 1; correct? 19 A. I -- you know, I answered the question. 20 I don't recall which IARC category that each of these 21 exposures is right off the top of my head. 22 Q. But do you say in the report that they are 23 judged to be causal by IARC; correct? 24 A. I do say that in my report. 25 Q. And IARC has not judged talc ovarian cancer</p>
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<p>1 BY MR. JAMES: 2 Q. Do you agree that, with a small association, 3 there's more concern for recall bias? 4 MS. PARFITT: Objection. 5 THE WITNESS: I think that with a 6 smaller association, there is more concern that it 7 could be due to bias from various reasons. 8 BY MR. JAMES: 9 Q. Can you cite to any scientific agency or 10 organization that has described the talc ovarian 11 cancer association as strong? 12 A. I do not recall anyone describing it that 13 way. 14 Q. Okay. And then we will turn now to page 12 15 of your report, Dr. Moorman, where you cite a number 16 of other exposures. 17 A. Yes. 18 Q. And do you see where I am? 19 A. Yes. 20 Q. And you say on page 12 that (as read): 21 "Well-accepted exposure to these 22 associations have relative risks 23 of similar magnitude and are 24 generally accepted to be causal." 25 Do you see where I was reading?</p>	<p>1 to be a causal association, has it? 2 A. As we have discussed several times today, 3 they describe it as possibly carcinogenic. 4 Q. Can you cite to any publication that assesses 5 the strength of an epidemiologic association by 6 considering "similar magnitude" odds ratios from 7 unrelated exposures to diseases? 8 A. I -- off the top of my head, I can't cite any 9 such publication. 10 Q. Have any scientific agencies that have looked 11 at this issue assessed strength of the talc ovarian 12 cancer relationship by considering similar magnitude 13 associations of unrelated exposures to diseases? 14 A. I know that in the Health Canada report, they 15 went through assessing the strength of the 16 association. I don't recall if they kind of 17 considered it in relation to other exposures that have 18 a similar magnitude of association. 19 Q. With regard to the associations that you have 20 identified on page 12, did you review the entire body 21 of scientific and medical literature pertaining to 22 those associations? 23 A. In -- let's see. Since when I cited these, 24 I did not go through the same level of detail like 25 I have done for the talc and ovarian cancer.</p>

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<p>1 The oral contraceptive use and breast cancer 2 that I cite, I was part of a team of researchers that 3 did a systematic review and meta-analysis of oral 4 contraceptives in relation to ovarian cancer as well 5 as breast cancer and some other cancers. 6 The other ones, again, I did not go in -- 7 did not review the body of literature in the same 8 detail as I did the talc and ovarian cancer. 9 Q. Did you assess, in any of these bodies of 10 literature, the risks for recall bias? 11 A. I did not. 12 Q. Did you consider, in these bodies of 13 literature, biologic mechanism for these five 14 exposures that you've identified? 15 A. I considered biologic mechanism, again, not 16 in the level of detail with the talc and ovarian 17 cancer. 18 Q. Did you assess them in a manner sufficient to 19 which you would opine in a published article or a 20 litigation report about the evidence supporting 21 causation? 22 A. I'm reading your question again. 23 Q. So am I. 24 A. I'm not sure. 25 Q. For these five exposures and diseases that</p>	<p>1 BY MR. JAMES: 2 Q. So in your report, when you are assessing 3 strength, and you discuss the fact that there are 4 similar magnitude odds ratios from other exposures 5 upon which one could conclude causation, you do not 6 also remark that there are similar magnitude ratios 7 upon one which could not conclude causation. 8 Why is that? Why did you lay out the 9 analysis this way? 10 A. What I was trying to do here is to make the 11 point that an association in the range of a 25 to 12 30 percent increased risk is something that there are 13 multiple examples of this being generally accepted as 14 a causal association. 15 I -- it was not my intent to describe the 16 entire universe of exposures and some that might be in 17 this range. 18 Q. There are certainly examples that you didn't 19 cite in the 1.2 to 1.3 range that are not causal; 20 right? 21 A. Did you have something specific in mind that 22 you are -- 23 Q. I'm asking you, actually. 24 Did you just go searching for similar 25 magnitude ratios upon which one could reach a</p>
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<p>1 you've cited on page 12, did you assess the body of 2 scientific and medical literature and evidence in a 3 manner sufficient to which you would feel comfortable 4 offering an opinion in the published literature or in 5 a litigation report about causation? 6 A. I think that I have answered the question 7 repeatedly that I did not do it in the detail that 8 I did the talc and ovarian cancer. If I were to put 9 in published literature or a litigation report, 10 I would want to make sure that I had done it as 11 absolutely thoroughly as possible. 12 Q. Your comparison of the odds ratios to these 13 five exposures -- you acknowledge that there are 14 exposures that you have not identified in your report 15 that are in the 1.2 to 1.3 range that are not causal 16 or have not proven to be causal; correct? 17 MS. PARFITT: Objection. Form. 18 THE WITNESS: I acknowledge that -- of 19 course, that there are reports of exposures that have 20 reported relative risk in this range, and it could 21 either be something that was associated with another 22 risk factor and it was not the causal factor or the 23 level of evidence was not adequate. Maybe people -- 24 there were fewer articles, people have not gone 25 through the whole evaluation of the causal criteria.</p>	<p>1 causation conclusion? 2 A. I -- I think that I was trying to get at that 3 is this association strong enough to be causal? And 4 we have evidence from these other exposures that, yes, 5 it's certainly possible. 6 The point is that you do not -- or you do 7 not dismiss an association of 1.25 or 1.3 as it 8 couldn't possibly be causal. We have evidence to 9 suggest that it -- there are many examples of it. 10 Q. But in your report, Dr. Moorman, you're not 11 just not dismissing it. You're not just using the 12 similar magnitude odds ratios to not dismiss the 13 possibility that this is a real association. You're 14 using the similar magnitude ratios in an effort to 15 ascribe strength to the association; correct? 16 A. Right. I am saying that I think this is 17 strong enough to be a real association, and I think 18 that we have other examples of similar magnitude 19 associations that are generally accepted as causal 20 associations. 21 Q. But if there are other odds ratios for other 22 exposures to diseases that you did not identify in 23 your report in the 1.2 to 1.3 range that are not 24 causal, then the magnitude ratio that you have here in 25 the top ovarian cancer literature, in that instance,</p>

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<p>1 is not strong enough to support causation?</p> <p>2 MS. PARFITT: Objection. Form.</p> <p>3 BY MR. JAMES:</p> <p>4 Q. I'll just restate it because it's confusing.</p> <p>5 A. Yeah, it is.</p> <p>6 Q. To support strength in your report, why do</p> <p>7 you select only similar magnitude ratios that, by your</p> <p>8 estimation, are Category 1 -- by your estimation, have</p> <p>9 been declared by IARC to be causal associations? Why</p> <p>10 do you only select associations by which one has -- by</p> <p>11 which IARC has concluded causation? Why don't you</p> <p>12 also acknowledge that there are associations of a</p> <p>13 similar magnitude that don't support causation?</p> <p>14 MS. PARFITT: Objection.</p> <p>15 THE WITNESS: I'm not really sure --</p> <p>16 I'm still not really sure what you're getting at with</p> <p>17 this question.</p> <p>18 I think that I was trying to make the point</p> <p>19 that the association we see here is strong enough to</p> <p>20 be accepted as a causal association. I'm not -- I'm</p> <p>21 not saying that every association of this magnitude</p> <p>22 has gone through the same process of assessing all of</p> <p>23 the Bradford Hill viewpoints and have come to the same</p> <p>24 conclusion, but I am saying that we have multiple</p> <p>25 examples of where an association of this magnitude is</p>	<p>1 Do you see where I'm reading that?</p> <p>2 A. Yes.</p> <p>3 Q. There, are you referring to epidemiologic</p> <p>4 literature?</p> <p>5 A. What -- you're taking one sentence and --</p> <p>6 I think that I discussed what I considered related to</p> <p>7 the passive smoke exposure and lung cancer and</p> <p>8 described it in more detail on page 13, the first full</p> <p>9 paragraph.</p> <p>10 Q. And is it fair to say that that body of</p> <p>11 evidence that you're referring to there is the</p> <p>12 epidemiologic literature?</p> <p>13 A. Yes.</p> <p>14 Q. You're not referring there to any sort of</p> <p>15 mechanistic studies or plausibility studies or</p> <p>16 anything like that; correct?</p> <p>17 A. No. I was looking at -- basically, I was</p> <p>18 comparing the two -- or the meta-analyses for the two</p> <p>19 topics.</p> <p>20 Q. On page 14, Dr. Moorman, you discuss the</p> <p>21 "prevalence of exposure."</p> <p>22 Do you see where I am? It's the --</p> <p>23 A. It's about halfway down?</p> <p>24 Q. Yeah, second full paragraph.</p> <p>25 A. Yes.</p>
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<p>1 causal.</p> <p>2 MS. PARFITT: Scott, is this a breaking</p> <p>3 point or no?</p> <p>4 MR. JAMES: How long have we been</p> <p>5 going?</p> <p>6 MR. FARIES: About an hour and 15.</p> <p>7 MS. BRENNAN: Yeah, we've been going</p> <p>8 about an hour and 15.</p> <p>9 MR. JAMES: Sure. Are we ready for a</p> <p>10 break?</p> <p>11 MS. PARFITT: Sure. Just a short one,</p> <p>12 yeah. Thank you.</p> <p>13 THE VIDEOGRAPHER: Going off the record</p> <p>14 at 4:33 p.m.</p> <p>15 (Recess taken from 4:33 p.m. to 4:46 p.m.)</p> <p>16 THE VIDEOGRAPHER: Back on record at</p> <p>17 4:47 p.m.</p> <p>18 BY MR. JAMES:</p> <p>19 Q. Dr. Moorman, on page 13 to 14 of your report,</p> <p>20 and really the top of page 14, you have a sentence</p> <p>21 stating that (as read):</p> <p>22 "The evidence for talc and ovarian</p> <p>23 cancer is as significant as for</p> <p>24 passive smoke exposure and lung</p> <p>25 cancer."</p>	<p>1 Q. And you say that it's critical to consider</p> <p>2 the prevalence of exposure in conjunction with</p> <p>3 considering strength; correct?</p> <p>4 A. I say (as read):</p> <p>5 "It's critical to consider the</p> <p>6 prevalence of the exposure in the</p> <p>7 population when evaluating its</p> <p>8 public health impact."</p> <p>9 Q. Before that, you say "in conjunction with the</p> <p>10 strength of the association." Right?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Do you think that the prevalence of</p> <p>13 exposure in the population, that that impacts your</p> <p>14 analysis on whether an association is strong or not</p> <p>15 strong?</p> <p>16 A. I think that the way that I stated it here</p> <p>17 is, you know, as an epidemiologist, a public health</p> <p>18 professional, I'm interested in the public health</p> <p>19 impact and how many cases of disease could be</p> <p>20 attributable to this exposure.</p> <p>21 So I go through and describe that factor</p> <p>22 that has a stronger association but is less common in</p> <p>23 the population could have potentially less public</p> <p>24 health impact than a risk factor that is -- doesn't</p> <p>25 have as high an odds ratio but you have many more</p>

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<p style="text-align: right;">Page 262</p> <p>1 exposed people in the population.</p> <p>2 Q. Moving on to consistency, Dr. Moorman, is</p> <p>3 consistency met on this body of literature?</p> <p>4 A. I do feel that consistency is met.</p> <p>5 Q. And on page 14, you -- I think it's page 14.</p> <p>6 Yes. In the first full paragraph, you discuss your --</p> <p>7 you see the last sentence of that paragraph, where you</p> <p>8 say (as read):</p> <p>9 "This observation has been quite</p> <p>10 consistent with findings</p> <p>11 replicated in studies conducted by</p> <p>12 different teams of investigators</p> <p>13 in different geographic locations</p> <p>14 and different race ethnic groups</p> <p>15 over a span of several decades."</p> <p>16 Do you see that?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Is that reflective of -- is that the basis</p> <p>19 upon which you conclude consistency is met?</p> <p>20 A. It is part of the basis of it. I think that,</p> <p>21 when we look at the overall meta-analyses, we look at</p> <p>22 the direction of the effect in all the studies and of</p> <p>23 these, like, 27 different studies, like, 90 percent of</p> <p>24 them show an increased -- or an odds ratio greater</p> <p>25 than 1.</p>	<p style="text-align: right;">Page 264</p> <p>1 cancer?</p> <p>2 A. They -- if we can go back to them, we see</p> <p>3 that there are multiple studies from the Nurses'</p> <p>4 Health Study, and then the Houghton study. They are</p> <p>5 showing a relative risk in most cases, I think, 1.12</p> <p>6 to 1.19. And, again, we have discussed some of the</p> <p>7 biases that might result in an attenuation of the</p> <p>8 association.</p> <p>9 And so I acknowledge that, with the</p> <p>10 exception of the serous invasive cancer in one of the</p> <p>11 studies, the associations have not been statistically</p> <p>12 significant, but they are certainly kind of in the</p> <p>13 direction of -- as the case-control studies.</p> <p>14 Q. Doctor, let's turn back briefly to the</p> <p>15 Houghton study. It's Exhibit 25.</p> <p>16 Are you with me?</p> <p>17 Dr. Moorman, if we look at the Houghton</p> <p>18 study on the first page in the results section of the</p> <p>19 abstract. Do you see where I'm looking?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. The authors there, they report</p> <p>22 every-use odds ratio as a 1.06.</p> <p>23 Do you see that?</p> <p>24 A. I do see that --</p> <p>25 Q. Okay. I'm running out of time, Dr. Moorman,</p>
<p style="text-align: right;">Page 263</p> <p>1 When we look at epidemiologic data, for</p> <p>2 reasons that we have discussed earlier today, it is</p> <p>3 very uncommon for every single study to reach the same</p> <p>4 conclusion. Some are going to have higher risk; some</p> <p>5 are going to be lower risk. And the level of</p> <p>6 consistency seen here, where virtually every study is</p> <p>7 showing an odds ratio greater than 1, I consider that</p> <p>8 quite consistent.</p> <p>9 Q. You understand that Bradford Hill, when he</p> <p>10 describes consistency, he talks about consistency</p> <p>11 across study design.</p> <p>12 Were you aware of that?</p> <p>13 A. Yes, I am. And I actually do -- the way that</p> <p>14 I described consistency, where even, you know -- two</p> <p>15 of the three cohort studies -- and we've already</p> <p>16 discussed the concerns I have about the Sister Study,</p> <p>17 which is really quite an outlier when we look at this</p> <p>18 whole body of literature. But both the Houghton study</p> <p>19 and the Nurses' Health Study, they are consistent in</p> <p>20 terms of the direction of the effect. And we have</p> <p>21 discussed the statistical significance at all.</p> <p>22 But in terms of the direction of the effect,</p> <p>23 I think that it is consistent.</p> <p>24 Q. So is your position that the cohorts</p> <p>25 demonstrate an association between talc and ovarian</p>	<p style="text-align: right;">Page 265</p> <p>1 so I really am going to ask you to answer my precise</p> <p>2 question.</p> <p>3 Do you see where the authors, they say</p> <p>4 there -- the authors say that it's "not associated</p> <p>5 with risk of ovarian cancer compared with never-use."</p> <p>6 Do you see that?</p> <p>7 A. Yes, that is what they state.</p> <p>8 Q. Okay. And 1.06 is -- again, it's not a</p> <p>9 statistically significant association; correct?</p> <p>10 A. With the confidence interval that they</p> <p>11 report. That's what tells you whether or not it's</p> <p>12 statistically significant. And with that confidence</p> <p>13 interval, no, it is not statistically significant.</p> <p>14 Q. And it's also very close to the null, isn't</p> <p>15 it?</p> <p>16 A. Yes. It's the 1.06, yes.</p> <p>17 Q. And the conclusion of the authors here is</p> <p>18 that (as read):</p> <p>19 "Perineal powder use does not</p> <p>20 appear to influence ovarian cancer</p> <p>21 risk."</p> <p>22 Correct?</p> <p>23 A. That's what they state, yes.</p> <p>24 Q. So this is one of the cohorts that you're</p> <p>25 talking about today; correct?</p>

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<p>1 A. Right. And --</p> <p>2 Q. And the authors here conclude that there's</p> <p>3 not an association between ovarian cancer risk and</p> <p>4 perineal talc use, don't they?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 THE WITNESS: Okay. Yes, I acknowledge</p> <p>7 that's their conclusion. And I think that -- I'm</p> <p>8 sorry -- the data that I was referring to comes from</p> <p>9 Table 3. And I, again, acknowledge that it was not</p> <p>10 statistically significant, but he said only genital</p> <p>11 powder use -- which is mostly what we're</p> <p>12 considering -- it had a hazard ratio of 1.4 or 1.3 --</p> <p>13 I'm sorry -- 1.14 or 1.13.</p> <p>14 And so, again, it's in the direction of</p> <p>15 effect, and, as we have discussed, biases could have</p> <p>16 led to some attenuation.</p> <p>17 BY MR. JAMES:</p> <p>18 Q. Are you saying that you believe that there's</p> <p>19 consistency among -- or between the case-control</p> <p>20 studies and the cohort studies in the talc ovarian</p> <p>21 cancer literature?</p> <p>22 A. I am saying that -- as I have pointed out</p> <p>23 here and with also the Nurses' Health Study, I am</p> <p>24 saying that there is consistency in the direction of</p> <p>25 the effect that they observed, and acknowledging that</p>	<p>1 right around 1. About half the studies have odds</p> <p>2 ratios greater than 1; about half have odds ratios</p> <p>3 less than 1. So in that case, I would say there is no</p> <p>4 consistency.</p> <p>5 I contrast it with this where, when you look</p> <p>6 at the forest plots from the meta-analyses, nearly all</p> <p>7 of the studies have odds ratios greater than 1.</p> <p>8 BY MR. JAMES:</p> <p>9 Q. And you're including in that testimony the</p> <p>10 cohort studies?</p> <p>11 A. Yes.</p> <p>12 Q. Odds ratios that are not statistically</p> <p>13 significant, in your mind, demonstrate consistency</p> <p>14 by -- among study design. Is that your testimony?</p> <p>15 MS. PARFITT: Objection. Form.</p> <p>16 THE WITNESS: I'm sorry --</p> <p>17 BY MR. JAMES:</p> <p>18 Q. Your testimony here today is that the results</p> <p>19 reached by the cohort studies and the case-control</p> <p>20 studies are consistent. Is that your testimony?</p> <p>21 A. My testimony, as I have stated repeatedly,</p> <p>22 that there is a great deal of consistency in the</p> <p>23 direction of the effect, that nearly all of the</p> <p>24 studies report an odds ratio greater than 1. And</p> <p>25 I acknowledge that not all studies are statistically</p>
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<p>1 these were not statistically significant findings.</p> <p>2 Q. So even though the authors report that</p> <p>3 there's not an association, you're claiming today that</p> <p>4 the cohort studies are consistent with the</p> <p>5 case-control studies in finding a association?</p> <p>6 MS. PARFITT: Objection. Form.</p> <p>7 THE WITNESS: I think that I have</p> <p>8 answered the question already that, in terms of the</p> <p>9 direction of the effect, that the Houghton study for</p> <p>10 the genital powder use and as well as some of the data</p> <p>11 from the Nurses' Health Study, it is consistent that</p> <p>12 there -- the odds ratio is greater than 1.</p> <p>13 BY MR. JAMES:</p> <p>14 Q. So as long as the odds ratio, even if it's</p> <p>15 statistically insignificant, exceeds 1, then you are</p> <p>16 claiming that that's reflective of an association that</p> <p>17 is consistent with the case-control studies?</p> <p>18 MS. PARFITT: Objection. Form.</p> <p>19 THE WITNESS: I am saying that there is</p> <p>20 consistency in the direction of the effect.</p> <p>21 If I may clarify. If you look at something</p> <p>22 like alcohol use and ovarian cancer, which is a fact,</p> <p>23 which overall there seems to be little association</p> <p>24 between alcohol and ovarian cancer, if you look at the</p> <p>25 meta-analyses from there, the overall estimate is</p>	<p>1 significant, but I'm just saying that the direction of</p> <p>2 the effect is very consistent.</p> <p>3 Q. And we talked earlier today about the Berge</p> <p>4 paper; correct?</p> <p>5 A. Yes, we did.</p> <p>6 Q. And they have performed an analysis for</p> <p>7 heterogeneity on the -- by study design; right?</p> <p>8 A. If I could go back to that.</p> <p>9 Q. Sure.</p> <p>10 A. Okay.</p> <p>11 Q. Dr. Moorman, if we look at the abstract of</p> <p>12 the paper, at the beginning, this is the point we</p> <p>13 discussed earlier. Here, the authors say (as read):</p> <p>14 "The heterogeneity of results by</p> <p>15 study design detracts from a</p> <p>16 causal interpretation."</p> <p>17 Correct?</p> <p>18 A. That is the statement that they make in their</p> <p>19 abstract, yes.</p> <p>20 Q. Okay. And then we looked earlier also at the</p> <p>21 Figure 2; correct?</p> <p>22 A. Yes, we did.</p> <p>23 Q. Okay. And, again, that reflects an analysis</p> <p>24 of the cohorts as compared to the case-controls;</p> <p>25 correct?</p>

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<p style="text-align: right;">Page 270</p> <p>1 A. Yes.</p> <p>2 Q. If you look at page 253 of the Berge article,</p> <p>3 and we look at the right column, the first -- the</p> <p>4 second full paragraph, the authors there state</p> <p>5 (as read):</p> <p>6 "The fact that the association</p> <p>7 between genital talc use and risk</p> <p>8 of ovarian cancer is present in</p> <p>9 case-control but not in cohort</p> <p>10 studies can be attributed to bias</p> <p>11 in the former type of studies."</p> <p>12 Do you see that?</p> <p>13 A. I do see what they say.</p> <p>14 I -- I think that they are not considering</p> <p>15 that there is also potential bias in the cohort</p> <p>16 studies. They say "bias in the former type of</p> <p>17 studies," not acknowledging the biases in the cohort</p> <p>18 studies.</p> <p>19 When you look at these data for the cohort</p> <p>20 studies, you look at the Gonzalez study, which again,</p> <p>21 I have referred to it as kind of an outlier with its</p> <p>22 relative risk of .73, there are many problems with</p> <p>23 that study. They assessed exposure in the past 12</p> <p>24 months. The level of exposure is very different than</p> <p>25 many of the other studies.</p>	<p style="text-align: right;">Page 272</p> <p>1 noted in some meta-analysis and</p> <p>2 reviews, there are considerations</p> <p>3 about those that should be taken</p> <p>4 into account."</p> <p>5 Q. Do you believe that there are inconsistencies</p> <p>6 in the literature with regard to dose-response? Yes</p> <p>7 or no.</p> <p>8 A. I think that, yes, that there -- that across</p> <p>9 the studies, some have found a dose-response, some</p> <p>10 have not.</p> <p>11 Q. At the bottom of page 30, you say that</p> <p>12 (as read):</p> <p>13 "When considering the studies that</p> <p>14 examine dose-response associations</p> <p>15 considering both dose and</p> <p>16 frequency to estimate the total</p> <p>17 number of applications of talc,</p> <p>18 the majority did find significant</p> <p>19 trends of higher risk with more</p> <p>20 lifetime applications of talc."</p> <p>21 Do you see that, where I read that?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And so for that proposition, you're</p> <p>24 citing to eight studies. If you look at the</p> <p>25 footnotes, you would agree with me that that's</p>
<p style="text-align: right;">Page 271</p> <p>1 And so part of the heterogeneity by study</p> <p>2 design could be attributed to this Gonzalez study that</p> <p>3 has very significant biases.</p> <p>4 Q. If other experts for Plaintiffs in this MDL</p> <p>5 litigation have conceded that there is not consistency</p> <p>6 between the cohorts and the case-controls, then you</p> <p>7 would differ with those experts; correct?</p> <p>8 MS. PARFITT: Objection. Form.</p> <p>9 THE WITNESS: I have --</p> <p>10 MS. PARFITT: Misstates the evidence.</p> <p>11 Thank you.</p> <p>12 THE WITNESS: I have answered the</p> <p>13 question, I think I've answered it repeatedly, why</p> <p>14 I think that the aspect of consistency is met.</p> <p>15 BY MR. JAMES:</p> <p>16 Q. Okay. On dose-response -- on page 30, you</p> <p>17 include discussion of dose-response in the literature.</p> <p>18 A. Yes.</p> <p>19 Q. And you acknowledge in your report that there</p> <p>20 are inconsistencies in reported dose-response;</p> <p>21 correct?</p> <p>22 A. I -- what I state is (as read):</p> <p>23 "While the inconsistency in</p> <p>24 reported dose-response trends for</p> <p>25 talc and ovarian cancer have been</p>	<p style="text-align: right;">Page 273</p> <p>1 reflective of eight studies cited; correct?</p> <p>2 A. Yes.</p> <p>3 Q. And you're saying that five of the eight</p> <p>4 studies that have looked at dose and frequency</p> <p>5 together did find significant trends; correct?</p> <p>6 A. Yes.</p> <p>7 Q. Among those studies that you cite for that</p> <p>8 proposition that the majority of those studies reflect</p> <p>9 a dose-response, you cited to the Mills study;</p> <p>10 correct?</p> <p>11 A. I believe so.</p> <p>12 MS. PARFITT: And, Dr. Moorman, you</p> <p>13 have your binder in front of you as well if you need</p> <p>14 it.</p> <p>15 MR. JAMES: Okay. I'm going to mark</p> <p>16 Mills as Exhibit 30.</p> <p>17 (Exhibit No. 30 was marked for identification.)</p> <p>18 BY MR. JAMES:</p> <p>19 Q. I'm going to hand you two copies.</p> <p>20 And, again, this is one of the papers you've</p> <p>21 cited for the proposition that there's a dose-response</p> <p>22 in the majority of studies that have looked at</p> <p>23 frequency times duration; correct?</p> <p>24 A. Okay. Yes.</p> <p>25 Q. And we're looking at Table 2 as the relevant</p>

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<p>1 table with the data; correct?</p> <p>2 A. Yes.</p> <p>3 Q. And if you look at Table 2, you go down to</p> <p>4 the cumulative use category, it says "frequency times</p> <p>5 duration"; correct?</p> <p>6 A. Yes.</p> <p>7 Q. And if I'm looking at this correctly,</p> <p>8 Dr. Moorman, doesn't the data in that table reflect an</p> <p>9 actual decrease in the odds ratio for the highest</p> <p>10 exposure category?</p> <p>11 MS. PARFITT: Objection. Form.</p> <p>12 THE WITNESS: It is -- the highest</p> <p>13 category, yes, does report an odds ratio of 1.06.</p> <p>14 BY MR. JAMES:</p> <p>15 Q. And based upon that, is it fair to say that</p> <p>16 this paper reflects a dose-response when measuring</p> <p>17 frequency times duration?</p> <p>18 A. They looked at the -- they did a test for</p> <p>19 trend, and we have a p-value of .051, so right at</p> <p>20 borderline statistically significant. Some people</p> <p>21 would argue that you should never use two decimal</p> <p>22 points for p-values. But nonetheless, it's -- the</p> <p>23 trend test was what I was referring to here, that it</p> <p>24 was right at borderline statistical significance.</p> <p>25 Q. And if you look at page 463 of the article,</p>	<p>1 Q. And they're not just acknowledging that</p> <p>2 there's not a perfect linear increase; they're saying</p> <p>3 that there's no dose-response for cumulative use.</p> <p>4 A. They say there is not a clear dose-response.</p> <p>5 I think -- you know, again, that's what they say. My</p> <p>6 conclusion here was, again, based on the test for</p> <p>7 trend that they did. I don't think that it was</p> <p>8 inaccurate, what I said here.</p> <p>9 Q. Another paper that you cite for the majority</p> <p>10 claim is the Terry 2013 paper; correct?</p> <p>11 A. Yes.</p> <p>12 Q. And do you know what the authors concluded in</p> <p>13 that paper about dose-response for cumulative use?</p> <p>14 A. May we look at that article?</p> <p>15 Q. Sure. It's Exhibit 24. And if we look at</p> <p>16 the abstract first together, the abstract says, the</p> <p>17 second sentence from the bottom (as read):</p> <p>18 "Among genital powder users, we</p> <p>19 observed no significant trend in</p> <p>20 risk with increasing number of</p> <p>21 lifetime applications assessed in</p> <p>22 quartiles."</p> <p>23 Did I read that correctly?</p> <p>24 MS. PARFITT: In the abstract?</p> <p>25 THE WITNESS: I'm sorry, I wasn't quite</p>
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<p>1 the third full paragraph down -- 463 in the left</p> <p>2 column -- the authors -- this is in the authors'</p> <p>3 words. They say (as read):</p> <p>4 "As in other studies, the present</p> <p>5 study did not find a clear</p> <p>6 dose-response based on duration of</p> <p>7 use or cumulative use."</p> <p>8 Do you see that?</p> <p>9 A. Right. And they go on to say that -- again,</p> <p>10 I was basing what I said here based on their test for</p> <p>11 trend, and -- and I think they do acknowledge that in</p> <p>12 that category where they had relatively few exposed</p> <p>13 cases, they didn't -- it was not a perfectly linear</p> <p>14 association.</p> <p>15 Q. So the authors are concluding that there's</p> <p>16 not dose-response for cumulative use; correct?</p> <p>17 MS. PARFITT: Objection.</p> <p>18 BY MR. JAMES:</p> <p>19 Q. Yes or no? That's what the authors conclude</p> <p>20 in the text that we just read together?</p> <p>21 A. I -- what we read -- yes. I'm trying --</p> <p>22 let's see.</p> <p>23 Yeah, I think that they are acknowledging</p> <p>24 that it was not a perfect linear increase. My report</p> <p>25 was basing it on the test for trend that they did.</p>	<p>1 there with you. Could you --</p> <p>2 BY MR. JAMES:</p> <p>3 Q. Understood. No worries.</p> <p>4 A. Okay.</p> <p>5 Q. So second sentence from the bottom of the</p> <p>6 abstract, the author's conclusions on dose-response</p> <p>7 are as follows (as read):</p> <p>8 "Among genital powder users, we</p> <p>9 observed no significant trend in</p> <p>10 risk with increasing number of</p> <p>11 lifetime applications assessed in</p> <p>12 quartiles."</p> <p>13 A. That's what they describe, and --</p> <p>14 Q. I just asked, is that -- did I read that</p> <p>15 correctly?</p> <p>16 A. You did read that correctly.</p> <p>17 Q. So the authors of the paper that you've cited</p> <p>18 as one of the five papers that finds dose-response by</p> <p>19 measuring lifetime of cumulative use says the exact</p> <p>20 opposite; correct?</p> <p>21 MS. PARFITT: Objection.</p> <p>22 THE WITNESS: If I may take just a</p> <p>23 moment. I want to find the part of this paper that</p> <p>24 supported the statement that I made in my report.</p> <p>25 MR. JAMES: Sure. Let's go off the</p>

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<p style="text-align: right;">Page 278</p> <p>1 record.</p> <p>2 THE VIDEOGRAPHER: Going off record at</p> <p>3 5:14 p.m.</p> <p>4 (Off the record.)</p> <p>5 THE VIDEOGRAPHER: Back on record at</p> <p>6 5:15 p.m.</p> <p>7 THE WITNESS: Okay. On page 817, it</p> <p>8 reads (as read):</p> <p>9 "Although a significant increase</p> <p>10 in risk with an increasing number</p> <p>11 of genital powder applications was</p> <p>12 found for non-mucinous epithelial</p> <p>13 ovarian cancer when non-users were</p> <p>14 included in the analysis."</p> <p>15 And it then goes on (as read):</p> <p>16 "Note trend in cumulative use was</p> <p>17 evident in analyses restricted to</p> <p>18 ever-users of genital powders."</p> <p>19 And so, again, my -- the statement that</p> <p>20 I had here, "a significant trend with increasing</p> <p>21 number of genital powder applications," they make the</p> <p>22 distinction of looking at the trend when you include</p> <p>23 non-users, and that's a pretty standard thing to do in</p> <p>24 epidemiology. It's -- you look -- can look as</p> <p>25 non-users as your reference group and then assess a</p>	<p style="text-align: right;">Page 280</p> <p>1 questions, Dr. Moorman.</p> <p>2 MR. JAMES: Michelle, is it fine if</p> <p>3 I have some time to review my notes while the others</p> <p>4 are asking questions and then come back?</p> <p>5 MS. PARFITT: Sure.</p> <p>6 MR. JAMES: Is that okay with you?</p> <p>7 MS. PARFITT: That's fine. Sure.</p> <p>8 MS. FOSTER: Can we go off and I'll</p> <p>9 switch.</p> <p>10 THE VIDEOGRAPHER: Going off the record</p> <p>11 at 5:18 p.m.</p> <p>12 (Off the record.)</p> <p>13 THE VIDEOGRAPHER: Back on record at</p> <p>14 5:20 p.m.</p> <p>15 CROSS-EXAMINATION BY COUNSEL FOR THE DEFENDANT</p> <p>16 IMERY'S TALC AMERICA, INC.</p> <p>17 BY MS. FOSTER:</p> <p>18 Q. Good evening, Dr. Moorman. We met a long</p> <p>19 time ago this morning. My name is Jennifer Foster.</p> <p>20 I represent one of the Defendants in this action,</p> <p>21 Imery's Talc America, Inc. Do you understand that?</p> <p>22 A. Yes, I do.</p> <p>23 Q. And before you got involved in this</p> <p>24 litigation, did you know who Imery's Talc America, Inc.</p> <p>25 was?</p>
<p style="text-align: right;">Page 279</p> <p>1 trend.</p> <p>2 I know what they say here, but I -- but</p> <p>3 I think that what I stated in my report is accurate,</p> <p>4 that they did find that a significant trend. So</p> <p>5 I don't think that I'm misstating what -- the data in</p> <p>6 the paper.</p> <p>7 BY MR. JAMES:</p> <p>8 Q. So the results that are reported by the</p> <p>9 authors in the abstract you disagree with; correct?</p> <p>10 MS. PARFITT: Objection. Form.</p> <p>11 BY MR. JAMES:</p> <p>12 Q. The statements in the abstract pertaining to</p> <p>13 dose-response, do you disagree with those statements?</p> <p>14 A. What they say is "among genital powder</p> <p>15 users." And so the statement that they make is</p> <p>16 accurate, but I think that they are citing data</p> <p>17 that -- it's one way to look at the data, but I think</p> <p>18 that considering the non-users in their test for trend</p> <p>19 is also a very well-accepted way to do that, to do a</p> <p>20 test for trend.</p> <p>21 And so I think that both -- they reported</p> <p>22 one aspect of their analysis, and I reported what</p> <p>23 I think accurately reflects another aspect of their</p> <p>24 analysis.</p> <p>25 Q. Okay. I am getting close to the end of my</p>	<p style="text-align: right;">Page 281</p> <p>1 A. No, I did not.</p> <p>2 Q. Had you ever heard of them before?</p> <p>3 A. No.</p> <p>4 Q. And do you have an understanding of who they</p> <p>5 are now that you've become involved in the litigation?</p> <p>6 A. I do.</p> <p>7 Q. And you understand that Imery's mines and</p> <p>8 supplies talc to Johnson & Johnson for use in some of</p> <p>9 its talcum powder products?</p> <p>10 A. That is my understanding, yes.</p> <p>11 Q. Do you understand that Imery's does not sell</p> <p>12 talcum powder products directly to consumers?</p> <p>13 A. That was my understanding, yes.</p> <p>14 Q. And based on some testimony earlier today</p> <p>15 about the basis of your opinions being grounded in</p> <p>16 epidemiology studies about talcum powder products, am</p> <p>17 I correct that you wouldn't have any personal</p> <p>18 knowledge with respect to the composition of the talc</p> <p>19 that Imery's mines and supplies to Johnson & Johnson?</p> <p>20 MS. PARFITT: Objection.</p> <p>21 THE WITNESS: No, I would not have that</p> <p>22 personal knowledge.</p> <p>23 BY MS. FOSTER:</p> <p>24 Q. And you have no opinions about any talc</p> <p>25 mining practices that Imery's employs; correct?</p>

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<p>1 A. I know nothing about their mining practices.</p> <p>2 Q. And you have no opinions about Imerys's</p> <p>3 compliance with any applicable standards or</p> <p>4 specifications regarding the mining of talc; correct?</p> <p>5 A. I do not know anything about that.</p> <p>6 Q. And I'm going to be hopping around a lot</p> <p>7 because Mr. James covered a lot of ground, so just</p> <p>8 bear with me. If I go somewhere and you don't know</p> <p>9 what I'm talking about, please just tell me you don't</p> <p>10 know what I'm talking about --</p> <p>11 A. Okay.</p> <p>12 Q. -- and I'll rephrase so that we can get on</p> <p>13 the same page.</p> <p>14 One of the first things you talked about</p> <p>15 this morning when you were talking to Mr. James is</p> <p>16 that you have entered a period I think you called</p> <p>17 preretirement transition. Do I have that right?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. And do you have a retirement date in</p> <p>20 mind?</p> <p>21 A. That's still somewhat being discussed with my</p> <p>22 husband.</p> <p>23 Q. Okay. So you don't have a set "I'm going to</p> <p>24 retire in a year," for example?</p> <p>25 A. The exact date is not defined yet.</p>	<p>1 A. Yes, that is.</p> <p>2 Q. And is that a study that's designed to</p> <p>3 collect new data from study participants, or is that</p> <p>4 going to be an evaluation of data that you already</p> <p>5 have collected from other studies?</p> <p>6 A. It is a consortium that is planning to</p> <p>7 analyze data that have already been collected. It</p> <p>8 involves -- I believe it is a total of seven studies;</p> <p>9 some case-control, some cohort studies.</p> <p>10 Q. And -- were you finished? I'm sorry.</p> <p>11 A. Go ahead.</p> <p>12 Q. And how were the studies selected to be</p> <p>13 included in that consortium?</p> <p>14 A. It was -- the purpose of that was to try to</p> <p>15 put more data together, especially related to women of</p> <p>16 African ancestry. So they're all US studies, so</p> <p>17 African American. Recognizing that the AACES study,</p> <p>18 with about 600 cases, we still have some issues with</p> <p>19 statistical power. So we contacted -- Dr. Schildkraut</p> <p>20 is the PI on this study as well.</p> <p>21 And so studies that had a reasonable number</p> <p>22 of African American study participants, they were</p> <p>23 contacted to see if they were interested in</p> <p>24 participating in such a study.</p> <p>25 And so it includes studies such as the Black</p>
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<p>1 Q. And when you do retire, are you still going</p> <p>2 to have any involvement with what you've defined as</p> <p>3 the AACES study, the African American Cancer</p> <p>4 Epidemiology Study?</p> <p>5 A. That is still to be determined as well.</p> <p>6 Q. And am I correct that that study is still</p> <p>7 ongoing?</p> <p>8 A. The funding for that study ended -- I think</p> <p>9 it was 2015/2016. I don't recall the exact date. And</p> <p>10 so we have not collected any data for that study since</p> <p>11 that time.</p> <p>12 We have continued to do analysis of data</p> <p>13 that we have collected, and we are also trying to</p> <p>14 secure funding to continue data collection with that</p> <p>15 study.</p> <p>16 Q. That was going to be my question. Who have</p> <p>17 you made that request to for additional funding?</p> <p>18 A. The grant application was submitted to</p> <p>19 National Cancer Institute.</p> <p>20 Q. And that's who funded the original research;</p> <p>21 correct?</p> <p>22 A. That is correct.</p> <p>23 Q. And you also mentioned a publication that is</p> <p>24 in draft form regarding something called the OCWAA</p> <p>25 Consortium; is that correct?</p>	<p>1 Women's Health Study Cohort, that's out of Boston</p> <p>2 University; the Multiethnic Cohort, which is out of</p> <p>3 California; the Southern Community Cohort Study; the</p> <p>4 Women's Health Initiative; as well as a Los Angeles</p> <p>5 case-control study and a case-control study out of</p> <p>6 Chicago, in addition to the AACES study.</p> <p>7 I think that that's most of them.</p> <p>8 Q. Okay. Are you involved in any current</p> <p>9 research where the intent is to collect new data for</p> <p>10 evaluation of risk factors for ovarian cancer?</p> <p>11 A. Other than what I described to you, that we</p> <p>12 hope to -- that we are applying for funding to</p> <p>13 continue the AACES study, I'm not currently doing any</p> <p>14 data collection related to ovarian cancers.</p> <p>15 Q. Are the coauthors and coinvestigators that</p> <p>16 you worked with on the AACES and the North Carolina</p> <p>17 Ovarian Cancer Study aware of your involvement in the</p> <p>18 talcum powder litigation?</p> <p>19 A. Some of them are. I -- you know, as --</p> <p>20 I have disclosed it on one publication, and if they've</p> <p>21 read it, they are aware. I've discussed it with some</p> <p>22 of them but not all of them. You know, I haven't had</p> <p>23 a conversation, per se, with all of them.</p> <p>24 Q. And you mentioned earlier, with respect to</p> <p>25 some of the new publications that are in draft form</p>

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<p>1 that are currently in the peer review process, that 2 they have talc as a -- as a confounding factor under 3 investigation; correct? 4 A. I think -- I'm going to reread your -- 5 Q. I can rephrase it. 6 I think when you were talking earlier about 7 the studies that you have in draft, the question was 8 whether or not you had any publications that, you 9 know, mentioned talc. And I thought your testimony 10 was that talc was listed as a possible confounding 11 factor in some of the studies that were in draft form. 12 Is that correct? 13 A. Right. I mentioned that specifically in 14 relation to the infertility and ovarian cancer paper 15 that is in draft form, it's -- talc is considered as a 16 confounder there. 17 In regard to the description of the OCWAA 18 study, that paper, we are listing it as one of the 19 factors that we are likely to evaluate as a risk 20 factor for ovarian cancer. 21 Q. Okay. And my question is have you ever 22 included asbestos as a risk factor under investigation 23 in your epidemiology studies? 24 A. If I am not mistaken, I think that we had a 25 question on the AACES questionnaire that we asked if</p>	<p>1 did you have a particular paper in -- in mind? 2 BY MS. FOSTER: 3 Q. Not with 20 minutes left, no. 4 A. I'm sorry. I just -- you know, you're asking 5 me what did they mean, and I'm not even sure which 6 paper might have described something as a weak 7 positive association, and I'm not sure who would have 8 used that terminology or what was going through their 9 mind when they chose those words. 10 Q. I assume there are standard epidemiology 11 textbooks that you use in your field; correct? 12 A. Yes. 13 Q. Okay. And what are some of your go-to 14 epidemiology textbooks? 15 A. Let's see. Ken Rothman's Modern Epidemiology 16 is -- different editions of it have been around since 17 I was in school 30 years ago. I still refer to that. 18 When I have taught the physician assistant 19 students, the textbook that we use, which is a little 20 bit lower-level textbook, was going to us. Those are 21 probably my go-to ones. 22 Q. Okay. Do any of the standard epidemiology 23 textbooks use terms like "weak," "modest," "strong," 24 to describe associations? 25 A. I -- I imagine that in the textbooks, they</p>
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<p>1 women had ever been -- ever had a job where they were 2 exposed to asbestos, and I don't know that we have 3 analyzed that data yet. 4 Q. Okay. And you had some discussion with 5 Mr. James earlier today about different types of 6 terminology that might be used to describe 7 associations in the epidemiology literature. 8 Do you recall that? 9 A. Yes. 10 Q. And you were talking about weak associations, 11 modest associations, strong associations. Do you 12 remember that general discussion? 13 A. Yes. 14 Q. Now, as an epidemiologist, how would you 15 define a weak positive association? 16 A. As we have said before, there is no absolute 17 cut-point what's a weak association, what's a modest, 18 what's a moderate association. I -- I can't put a 19 number on that. I don't think any epidemiologist 20 could. 21 Q. In papers that you've authored that have used 22 the words "weak positive association," what do the 23 authors mean by that? 24 MS. PARFITT: Objection. Form. 25 THE WITNESS: I'm -- I'm not -- if --</p>	<p>1 might use that. But the point that I have been trying 2 to make is that there is no numerical value to go 3 along with those descriptors. 4 Q. All right. Switching topics, I want to talk 5 a little bit about some of the things that you 6 reviewed before you came and gave your deposition 7 today. 8 Now, you confirmed earlier that you reviewed 9 the reports of some of the other Plaintiffs' experts 10 in this case; correct? 11 A. Yes. 12 Q. And you reviewed those all between the time 13 that you finished your report and when you came here 14 to testify; correct? 15 A. That is correct. 16 Q. And those were all provided to you by 17 Plaintiffs' counsel; correct? 18 A. That is correct. 19 Q. And how did you choose which of the 22 expert 20 reports that you were going to sit down and read? 21 A. I knew which of the ones that were more of 22 the epidemiology-focused ones. And because that is my 23 area of expertise, those were the ones that I went to 24 first. 25 Also, some of it was, you know, some of the</p>

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<p style="text-align: right;">Page 290</p> <p>1 names that I recognized: David Kessler, former chair 2 of the -- former head of the FDA; Daniel 3 Clarke-Pearson, who is a gynecologic oncologist who 4 was formerly at Duke. He's now at UNC. 5 Q. Do you know Dr. Clarke-Pearson? 6 A. Only by reputation. 7 Q. You haven't talked to him about your opinions 8 in this litigation? 9 A. No, I have not. 10 Q. And you haven't talked to any other 11 Plaintiffs' expert about your opinions in this 12 litigation? 13 A. No, I have not. 14 Q. In reviewing those reports, did you work 15 under the assumption that the authors of those reports 16 had employed generally accepted methodologies in 17 forming their conclusions? 18 A. I -- I assumed that they had. You know, some 19 of the experts, they are names that I know, even if 20 I don't know the individual personally. You knows, 21 Dr. Siemiatycki, Dr. McTiernan, these are very 22 well-known epidemiologists. And so my assumption is 23 that they use generally accepted methodologies. 24 Q. I noticed on the 25 additional-materials-provided list -- I think it was</p>	<p style="text-align: right;">Page 292</p> <p>1 2016, and then updated it to make sure that my report 2 reflected the current literature. 3 Q. Did you do any kind of Bradford Hill analysis 4 of the claimed association between talcum powder usage 5 and ovarian cancer before you were retained as an 6 expert in the talcum powder litigation? 7 A. Doing -- considering the talcum powder -- or 8 considering the Bradford Hill criteria, this is 9 something that we do in our work all the time. It's 10 probably not as formalized as what was done here. 11 As you're aware, I was a coauthor, but I was 12 not the lead author on the AACES study of talc and 13 ovarian cancer. And in regard to the North Carolina 14 Ovarian Cancer Study, that was not the major focus of 15 the -- those papers that reported on talc and -- that 16 reported on talc as a risk factor. 17 So have I done the Bradford Hill criteria? 18 Certainly not in the detail that I have done for the 19 report that I prepared. 20 Q. And when you were -- when Mr. James asked you 21 about the NCI PDQ -- and you all looked at that as an 22 exhibit to the deposition. 23 Do you recall that earlier today? 24 A. Yes, I do. 25 Q. And one of the things that you mentioned is</p>
<p style="text-align: right;">Page 291</p> <p>1 marked as Exhibit 8 earlier. It's a document that 2 I believe you said counsel had prepared, and it has 3 the expert reports on it. It also has a couple of 4 deposition transcripts on it from Dr. Plunkett and 5 Dr. Singh. 6 Did you review either of those before you 7 came and testified today? 8 A. Dr. Plunkett and Dr. Singh, S-I-N-G-H? 9 Q. Yes. 10 A. I don't believe that I read Dr. Plunkett's 11 deposition. I did read a fair bit of Dr. Singh's 12 deposition. 13 Q. When did you do that? 14 A. Probably a week or so ago. 15 Q. Do you have any intention of reading the rest 16 of the reports that Plaintiffs' counsel sent to you 17 after you're closed here today? 18 A. I think that it is possible that I will read 19 some of them, time permitting. 20 Q. You testified about a literature search that 21 you conducted on talcum powder and ovarian cancer. 22 When did you first conduct that search? 23 A. I believe that probably the first time I did 24 that search was not long after I was contacted about 25 possible involvement in this. So probably summer of</p>	<p style="text-align: right;">Page 293</p> <p>1 you see some kind of inconsistency in the way that NCI 2 evaluates data as to whether there is adequate 3 evidence of association or inadequate evidence of 4 association and specifically used the example of the 5 way that that they evaluated the breastfeeding data. 6 Do you remember that? 7 A. Right. What I -- I think the point that 8 I was trying to make when I was asked about that is 9 that the NCI PDQ, they do not describe their 10 methodology. So we're kind of left at what method did 11 they use to evaluate the data? Did they do a complete 12 systematic review, or was it -- was it something less 13 than a complete systematic review? 14 And my point is that, from the information 15 provided, we don't know what methods they used. 16 Q. Have you ever tried to communicate with any 17 of the editorial board members who write the NCI PDQ? 18 A. No, I have not. 19 Q. And you haven't submitted your report to 20 IARC; correct? 21 A. My -- 22 Q. Your expert report. You haven't submitted a 23 copy of your expert report to IARC for their 24 consideration; correct? 25 A. No, I have not.</p>

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<p>1 Q. Being conscious of the fact that we have</p> <p>2 limited time left, I'm going to -- okay. One last</p> <p>3 question.</p> <p>4 In terms of the expert report that you</p> <p>5 provided in the MDL litigation that we've been talking</p> <p>6 about all day today, are all of the opinions that you</p> <p>7 intend to give in this litigation contained within</p> <p>8 that report?</p> <p>9 A. I believe they are, yes.</p> <p>10 MS. FOSTER: I don't have anything else</p> <p>11 for you. So I'm going to pass you on to my colleague</p> <p>12 here. Thank you very much.</p> <p>13 THE WITNESS: Okay.</p> <p>14 CROSS-EXAMINATION BY COUNSEL FOR THE DEFENDANTS</p> <p>15 PERSONAL CARE PRODUCTS COUNCIL</p> <p>16 BY MS. APPEL:</p> <p>17 Q. Hi, Dr. Moorman. You can you hear me okay?</p> <p>18 A. I can, yes.</p> <p>19 Q. And just as a reminder from this morning,</p> <p>20 I am Renée Appel, and I represent Personal Care</p> <p>21 Products Council. And I just have a handful of</p> <p>22 questions to follow up on.</p> <p>23 When did you first form your opinion in your</p> <p>24 expert report that talcum powder products can cause</p> <p>25 ovarian cancer?</p>	<p>1 referring to talcum powder products?</p> <p>2 A. Yes, because all of the literature is -- the</p> <p>3 epidemiologic literature is based on talcum powder</p> <p>4 products, whatever the women reported that they used.</p> <p>5 Q. So is it correct, Dr. Moorman, that you had</p> <p>6 not formed an opinion as to whether pure talc is a</p> <p>7 risk factor for forming ovarian cancer?</p> <p>8 MS. PARFITT: Objection.</p> <p>9 THE WITNESS: Again, my opinion is</p> <p>10 based on the product that women have used, and my</p> <p>11 understanding is that all of the products, they have</p> <p>12 other constituents in them. So they may contain, you</p> <p>13 know, as we have discussed previously, fragrances, for</p> <p>14 example. We have also talked about that there are</p> <p>15 other -- there's evidence to suggest other</p> <p>16 constituents, such as asbestos or possibly heavy</p> <p>17 metals.</p> <p>18 BY MS. APPEL:</p> <p>19 Q. And as to those constituents, would you defer</p> <p>20 to other experts to opine on them, based on the</p> <p>21 examples you just provided, fragrances or heavy</p> <p>22 metals?</p> <p>23 MS. PARFITT: Objection. Form.</p> <p>24 THE WITNESS: You're asking me defer to</p> <p>25 other estimates to opine on them in what sense? Opine</p>
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<p>1 A. I think that we have talked about this, that</p> <p>2 the literature on talc and ovarian cancer has been</p> <p>3 accruing since 1982, and to say at what point I formed</p> <p>4 my opinion that it causes ovarian cancer, I can't</p> <p>5 pinpoint that date.</p> <p>6 I can say that I have considered talc as a</p> <p>7 risk factor for ovarian cancer for quite some time.</p> <p>8 Just over my career, it just seems like it has been an</p> <p>9 accumulating volume of evidence.</p> <p>10 Q. Did you hold that opinion before you were</p> <p>11 retained as an expert in the talc litigation dating</p> <p>12 back to the Ingham case?</p> <p>13 A. I think that, yes, I did.</p> <p>14 Q. But, sitting here today, you can't recall a</p> <p>15 specific year or point in time in which you formed</p> <p>16 that opinion?</p> <p>17 MS. PARFITT: Objection.</p> <p>18 THE WITNESS: I think that I've</p> <p>19 answered that. I can't pinpoint at what point that</p> <p>20 I concluded it was a risk factor for ovarian cancer.</p> <p>21 It's been something that I've considered a risk factor</p> <p>22 for ovarian cancer for quite -- quite a number of</p> <p>23 years.</p> <p>24 BY MS. APPEL:</p> <p>25 Q. And when you refer to "it," Doctor, are you</p>	<p>1 on them in what sense?</p> <p>2 BY MS. APPEL:</p> <p>3 Q. Sure. Would you defer to other experts to</p> <p>4 opine on whether those particular constituents in</p> <p>5 isolation are a risk factor for ovarian cancer?</p> <p>6 MS. PARFITT: Objection. Form. Asked</p> <p>7 and answered.</p> <p>8 THE WITNESS: Okay. Those particular</p> <p>9 constituents in isolation are a risk factor for</p> <p>10 ovarian cancer.</p> <p>11 I think that we have discussed this</p> <p>12 previously today, that what is the evidence about, for</p> <p>13 example, the heavy metals in isolation in ovarian</p> <p>14 cancer and limited to -- limited epidemiologic data in</p> <p>15 that regard.</p> <p>16 So I don't know that I'm deferring to other</p> <p>17 experts, but, as I phrased it earlier today, I --</p> <p>18 the -- whether or not these substances are in talc</p> <p>19 products, it adds to the biologic plausibility, but</p> <p>20 the epidemiologic data is based on the talc products.</p> <p>21 That's what the women were exposed to.</p> <p>22 BY MS. APPEL:</p> <p>23 Q. Okay. So in forming your opinion, you are</p> <p>24 assuming that those constituents that you've</p> <p>25 mentioned -- heavy metals, asbestos -- that they are</p>

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<p>1 in the talc powder product that you've rendered an 2 opinion about today? 3 MS. PARFITT: Objection. Misstates her 4 earlier opinions. 5 You might want to read that. 6 THE WITNESS: I -- I am not making, 7 really, any assumptions that these are in the 8 products. My -- you know, my focus on the 9 epidemiologic data is based on the use of the talc 10 products, whatever is contained in them. 11 BY MS. APPEL: 12 Q. In your report on page 30, you've indicated 13 that -- second paragraph, I'm reading from. And I'll 14 give you a moment to turn to it. (As read): 15 "For an association like talc and 16 ovarian cancer, the dose that is 17 most relevant is the amount of 18 talc that actually reaches the 19 fallopian tubes and ovaries." 20 Did I read that correctly? 21 A. Yes, you did. 22 Q. There is, in fact, though, no dose that has 23 been determined that actually reaches the fallopian 24 tubes and the ovaries in any of the studies that 25 you've relied upon; correct?</p>	<p>1 MS. PARFITT: Objection. Form. 2 THE WITNESS: I think that the sentence 3 that followed the one that you're reading is that, for 4 all the pragmatic reasons, we rely on the measures of 5 external application as a surrogate of the level of 6 exposure. There's no way that we could measure what 7 dose of talc reached the ovaries or the fallopian 8 tubes for something that women might have applied over 9 20, 30, 40 years of their lives. 10 BY MS. APPEL: 11 Q. Earlier today, you had discussed the 12 hierarchy of scientific evidence. 13 Do you recall that discussion? 14 A. I don't think that I used that terminology, 15 but I think that -- in talking about the 16 meta-analyses, yes. Yes. 17 Q. In terms of that hierarchy, that you 18 understand that I'm referring to based on that prior 19 discussion, where do cohort studies fall in comparison 20 to case-control studies? 21 MS. PARFITT: Objection. Asked and 22 answered. 23 THE WITNESS: Okay. If you have a 24 cohort study that was able to determine exposure 25 completely and accurately, and follow women for a</p>
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<p>1 MS. PARFITT: Objection. Form. 2 THE WITNESS: Let's see. 3 BY MS. APPEL: 4 Q. I can rephrase if you don't understand. 5 A. If you wouldn't mind, please. 6 Q. Absolutely. 7 In the studies that you've relied upon in 8 forming your opinion, none of those studies have 9 determined a particular dose of talc that actually 10 reaches the fallopian tubes and ovaries; correct? 11 MS. PARFITT: Objection. 12 THE WITNESS: Okay. So if we are 13 talking about the epidemiologic studies, there -- no, 14 of course, they did not measure what dose of talc 15 reached the ovaries and fallopian tubes. That would 16 not be feasible to do for -- reflecting the many, many 17 years of use, and also it would be completely 18 unfeasible to do something like that in an 19 epidemiologic study. 20 BY MS. APPEL: 21 Q. But you maintain the opinion that a 22 determination of that amount -- the amount being what 23 talc reaches the fallopian tubes and ovaries -- is 24 important to making a determination about an 25 association between talc and ovarian cancer; correct?</p>	<p>1 sufficient period of time, I think most people would 2 consider that a -- generally a stronger design than a 3 case-control study. 4 But, as I have indicated in my report, you 5 can't rely just on what is the stronger study design, 6 in general. You look -- have to look at the strengths 7 and limitations of the individual studies. 8 Cohort studies have some strengths; they 9 have some notable weaknesses. And I've described 10 those weaknesses several times over the course of 11 today. And I also acknowledge that case-control 12 studies have some weaknesses, but they also have 13 noticeable strengths too. 14 BY MS. APPEL: 15 Q. Is it accurate, Dr. Moorman, that, when you 16 were previously discussing meta-analyses and where 17 that falls on the hierarchy, you were envisioning a 18 pyramid graphic? Is that correct? 19 A. I have -- yes, I have seen graphics that 20 depict it like that. 21 Q. And in those particular graphics, where is 22 cohort studies listed in comparison to case-control 23 studies? 24 MS. PARFITT: Objection. 25 THE WITNESS: As I have said, that in</p>

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<p style="text-align: right;">Page 302</p> <p>1 that pyramid, it is -- typically, the cohort study is 2 ranked as a stronger study design. But, again, I 3 cannot emphasize strongly enough that you have to 4 consider strengths and weaknesses of individual. 5 BY MS. APPEL: 6 Q. And, Dr. Moorman, have you considered 7 publishing your expert report or the findings that you 8 arrived at in your expert report? 9 A. I have considered it. I have not actually 10 done anything to translate it into a manuscript. 11 MS. APPEL: Okay. Thank you, 12 Dr. Moorman. That concludes my questions. 13 THE WITNESS: Okay. 14 MR. JAMES: I think there's about eight 15 minutes. Off the record. 16 THE VIDEOGRAPHER: Going off the record 17 at 5:50 p.m. 18 (Discussion off the record.) 19 THE VIDEOGRAPHER: Back on record at 20 5:51 p.m. 21 FURTHER EXAMINATION BY COUNSEL FOR THE 22 JOHNSON & JOHNSON DEFENDANTS 23 BY MR. JAMES: 24 Q. Dr. Moorman, in regard to your general cause 25 opinion, do you hold the opinion that the evidence is</p>	<p style="text-align: right;">Page 304</p> <p>1 is sufficient to conclude that inhaled talcum powder 2 can cause ovarian cancer? 3 A. I do not think that there are epidemiologic 4 studies that have actually looked at inhaled talcum 5 powder in relation to ovarian cancer. 6 Q. And so is your answer that -- let me just ask 7 this again. 8 Do you believe there's sufficient evidence 9 upon which you can conclude that inhaled talc powder 10 causes ovarian cancer? 11 MS. PARFITT: Objection. 12 THE WITNESS: I think that I answered 13 that when I said that I don't think that there are 14 epidemiologic studies that have looked at that. So 15 I can't say that there is sufficient evidence. 16 BY MR. JAMES: 17 Q. Dr. Moorman, are you generally aware that, in 18 the African-American population, there is a lower 19 incidence of ovarian cancer? 20 A. Yes. 21 Q. And you have -- have you also seen in the 22 literature that there is at least some discussion in 23 the literature that the prevalence of talcum powder 24 used in the African-American populations may be 25 higher?</p>
<p style="text-align: right;">Page 303</p> <p>1 sufficient to support a general cause opinion for all 2 subtypes of ovarian cancer or do you distinguish among 3 the subtypes? 4 A. Okay. The majority of the studies looked at 5 epithelial ovarian cancer as a whole. Some of the 6 studies did look at subtypes. As we are aware, the 7 serous subtype is the vast majority, probably about 8 60 -- maybe "vast majority" is overstating it. But 9 serous subtypes are roughly 60 percent of ovarian 10 cancer cases. And so the studies that looked at the 11 subtypes tended to focus on that. 12 The other subtypes -- the mucinous, the 13 clear cell, and the other subtypes -- they are a much 14 smaller percentage of epithelial ovarian cancer. And 15 so there's really not adequate data to make a 16 conclusion about these subtypes. 17 Q. With regard to inhalation, which you touch 18 upon in your report, do you hold the opinion that 19 inhalation of talcum powder products can cause ovarian 20 cancer? 21 A. I have stated that that is a possible route 22 of exposure to the ovaries. The epidemiologic studies 23 have not specifically addressed the risk associated 24 with inhalation only of talcum powder products. 25 Q. So is there evidence upon which you believe</p>	<p style="text-align: right;">Page 305</p> <p>1 A. Yes. 2 Q. If both of those things are true, can you 3 provide us an explanation as to why -- why that would 4 be the case? 5 A. There are many causes of ovarian cancer. And 6 some of the risk factors are more common in 7 African-American women; some are less common. 8 So when you consider the whole spectrum of 9 risk factors, you know, breastfeeding, pregnancy, oral 10 contraceptive use, to pinpoint one factor like talc 11 that is used more frequently in African Americans and 12 then say that that conflicts with the lower incidence 13 of ovarian cancer that we see in African-American 14 women, it doesn't take into account the full spectrum 15 of risk factors. 16 Q. With regard to the Health Canada assessment 17 that we discussed much earlier today, do you 18 understand that that assessment is in draft form 19 currently? 20 MS. PARFITT: Objection. 21 THE WITNESS: My understanding is that 22 the scientific assessment they did is complete and 23 that they are -- that there is a period of comment 24 that -- so, I'm sorry, I want to make sure... 25</p>

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<p>1 BY MR. JAMES: 2 Q. Do you understand that right now that 3 assessment is currently in the process of a comment 4 period? 5 MS. PARFITT: Objection. Form. 6 THE WITNESS: My understanding is the 7 assessment of the risk that they did, that is 8 complete, and then they are assessing -- or it is in a 9 comment period. And I think that, you know, 10 potentially, if there were some serious concerns 11 raised, they might revisit the risk assessment that 12 they did. But my understanding is what they published 13 is their -- that they felt like the risk assessment 14 was complete. 15 BY MR. JAMES: 16 Q. And to be very quick here, I understand that 17 one of the materials provided to you in the additional 18 materials list was the Taher paper; correct? 19 A. Yes. 20 Q. And do you understand that the Taher paper is 21 one of the items discussed in the Health Canada 22 assessment? 23 A. Yes. 24 Q. And do you understand the Taher paper's 25 conclusion is consistent with the IARC's conclusion of</p>	<p>1 A. Yes, I -- 2 MS. PARFITT: Is the question is that 3 what it says? 4 BY MR. JAMES: 5 Q. That is the question. 6 We had a discussion earlier today about 7 possible cause; correct? 8 A. Yes. 9 MS. PARFITT: Objection. 10 BY MR. JAMES: 11 Q. And, Dr. Moorman, with respect to the 12 Bradford Hill analysis -- 13 MS. PARFITT: Can we stop for a minute? 14 Are you going to tell us when we're off and 15 when we're done? 16 THE VIDEOGRAPHER: Just one minute. 17 MS. PARFITT: Thank you. Oh, that's 18 good. 19 BY MR. JAMES: 20 Q. With respect to your Bradford Hill 21 analysis -- and this should be my last question -- 22 A. Okay. 23 Q. -- you will agree with me that in order to 24 reach a causal conclusion, you must rely on items 25 other than the cohorts, case controls, and</p>
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<p>1 possible cause? 2 MS. PARFITT: Objection. Form. 3 Misstates the evidence. 4 THE WITNESS: If you have the Taher 5 paper -- again, just recalling exactly what they 6 stated, I -- too many papers to remember all the 7 detail. 8 BY MR. JAMES: 9 Q. When is the last time you reviewed the Taher 10 paper? 11 A. I would say probably a week or two ago. 12 MR. JAMES: So if Michelle doesn't cut 13 me off, I will hand you a copy of it. I'm going to 14 mark it as Exhibit 31. 15 (Exhibit No. 31 was marked for identification.) 16 BY MR. JAMES: 17 Q. I'll hand you two copies. 18 Okay. And, Dr. Moorman, again, because I'm 19 running out of time, I'll direct you to the precise 20 portion of the article that founds my question. It's 21 on page 49, and it's in the conclusion section of the 22 paper. 23 And you see in the last sentence -- in the 24 last sentence, they report that the data indicates 25 "possible cause of ovarian cancer"?</p>	<p>1 meta-analyses of the epidemiologic literature; 2 correct? 3 MS. PARFITT: Objection. Form. 4 THE WITNESS: The -- some of the 5 Bradford Hill aspects which I think I discussed in my 6 report were the biological plausibility, and so I did 7 rely on literature other than the epidemiologic 8 literature. 9 BY MR. JAMES: 10 Q. And those are necessary as part of your 11 methodology to reach a causal conclusion; correct? 12 MS. PARFITT: Objection. Form. 13 THE WITNESS: They are a consideration. 14 When you do a Bradford Hill analysis, of course you 15 take into account the biological plausibility and the 16 data that may come from cancer biology studies, animal 17 studies, and so on. So yes, it should be considered. 18 MR. JAMES: Okay. Dr. Moorman, thank 19 you for your time. 20 THE WITNESS: Okay. 21 MS. PARFITT: Can we go off the record, 22 please. 23 THE VIDEOGRAPHER: Going off the record 24 at 6:01 p.m. 25 (Recess taken from 6:01 p.m. to 6:14 p.m.)</p>

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<p>1 THE VIDEOGRAPHER: Back on record at 2 6:15 p.m. 3 CROSS-EXAMINATION BY COUNSEL FOR THE PLAINTIFF 4 BY MS. PARFITT: 5 Q. Dr. Moorman, good evening. 6 A. Good evening. 7 Q. I just have a few questions to follow up with 8 counsel for J&J and then for PCPC. 9 Dr. Moorman, you were asked not too long ago 10 by Mr. James a question with regard to your general 11 causation opinions as they relate to does talc -- do 12 talcum powder products cause ovarian cancer. 13 Do you remember that discussion? 14 A. Yes, I do. 15 Q. All right. And I believe the question dealt 16 with subtypes of epithelial ovarian cancer. 17 Do you remember that? 18 A. Yes. 19 Q. All right. And I believe your testimony was 20 that there's really not adequate data to make a 21 conclusion about the subtypes. 22 Did you mean, when you said that, that 23 there's not adequate data to make a conclusion about 24 these other subtypes, that that was because the 25 non-serous subtypes were relatively rare?</p>	<p>1 of the opinion of Health Canada vis-à-vis exposure to 2 talcum powder products and ovarian cancer? 3 A. My -- my understanding is that Health Canada 4 indicated that talcum powder products can cause 5 ovarian cancer. 6 Q. Mr. James showed you a study, the Taher 7 study. 8 A. Yes. 9 Q. And you had an opportunity to review the 10 Taher study as well; correct? 11 A. Yes. 12 Q. Is the Taher study a -- one of the pieces of 13 evidence that you looked at in your review of the 14 Health Canada assessment? 15 A. One of -- it's one of the pieces of evidence, 16 but not the sole body of evidence that they 17 considered. 18 Q. Okay. And is the Taher study also considered 19 a meta-analysis? 20 A. Yes. 21 Q. Okay. For purposes of rendering your 22 opinions in this case, that talcum powder products can 23 cause ovarian cancer, you have shared with the ladies 24 and gentlemen of the jury that you have reviewed 25 multiple meta-analyses; correct?</p>
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<p>1 A. Yes, but the bulk of the literature is 2 addressing epithelial ovarian cancer, which includes 3 all of the subtypes. 4 Q. All right. So that the ladies and gentlemen 5 are clear as to what your opinion is, is it your 6 opinion that talcum powder products can cause -- or 7 exposure -- let me strike that. 8 Is it your opinion that exposure to talcum 9 powder products can cause ovarian cancer? Is that 10 your opinion? 11 A. That is my opinion. 12 Q. All right. And does that include all types 13 of epithelial ovarian cancer? 14 A. That -- yes. The data are based -- are 15 largely based on all types of epithelial ovarian 16 cancer. Yes. 17 Q. You were questioned a little earlier, and 18 briefly, about the Health Canada assessment. Do you 19 recall those discussions? 20 A. Yes. 21 Q. Okay. And have you had an opportunity to 22 review the recommendations of Health Canada? 23 A. I have, yes. 24 Q. All right. Based upon your review of the 25 Health Canada assessment, what is your understanding</p>	<p>1 A. That is correct. 2 Q. And I believe you spent time today talking 3 with us with regard to the various meta-analyses that 4 you've looked at, examined, and assessed; correct? 5 A. That is correct. 6 Q. Okay. Based upon the totality of the 7 meta-analyses that you have reviewed, what is your 8 opinion with regard to whether or not they demonstrate 9 that talcum powder products can cause ovarian cancer? 10 A. I think that the meta-analyses show 11 consistent conclusions of a 25 to 30 percent increased 12 risk for ovarian cancer; and that coupled with the 13 other criteria that I considered -- the biological 14 plausibility and the various other Bradford Hill 15 criteria -- that I came to the conclusion that talc is 16 a cause of ovarian cancer. 17 Q. Dr. Moorman, is it fair to say that the 18 method -- method of review and your methodology and 19 the analysis that you performed, for purposes of the 20 preparation of your report and the opinions that you 21 shared today, is the type of methodology and the type 22 of process that is generally accepted in your 23 scientific community of epidemiologists? 24 MS. FOSTER: Objection to form. 25 THE WITNESS: I think that the methods</p>

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<p>1 that I used are what I do routinely in my work as an 2 epidemiologist and that is routinely done when we 3 conduct systematic reviews. 4 BY MS. PARFITT: 5 Q. You were questioned numerous times today with 6 regard to the IARC review of talcum powder products 7 and ovarian cancer. Do you recall those discussions? 8 A. Yes, I do. 9 Q. The IARC committee put out a monograph in 10 2010. Is that your understanding? 11 A. That is my understanding, yes. 12 Q. Do you have any knowledge as to when the IARC 13 committee met to make their findings as it pertained 14 to the role of talcum powder products in ovarian 15 cancer? 16 A. I don't recall the exact date, but I believe 17 that it was quite a bit earlier than that. I'm not 18 sure of the exact date. 19 Q. Okay. But it preceded the monograph that 20 came out in 2010? 21 A. Yes. 22 MS. PARFITT: Dr. Moorman, I have no 23 further questions. Thank you very much. I appreciate 24 it. A long day. 25 MR. JAMES: Dr. Moorman, just a handful</p>	<p>1 A. The most pronounced difference that we are 2 aware of is that smoking seems to be more strongly 3 associated with mucinous ovarian cancer than with 4 other subtypes. 5 But in most -- for most other risk factors, 6 there -- the risk factors seem to be pretty consistent 7 across the subtypes. 8 Q. Are you aware that many clinicians consider 9 the various subtypes of ovarian cancer to be different 10 diseases? 11 MS. PARFITT: Objection. Form. 12 THE WITNESS: I think that clinicians 13 recognize that they -- there are differences. Again, 14 going to pathologists, they can distinguish between 15 them. 16 But in terms of how they treat them, it's 17 my -- I'm not aware of any real difference in how they 18 would treat the different subtypes of ovarian cancer. 19 BY MR. JAMES: 20 Q. And other than smoking, which is the factor 21 that you just mentioned, can you think of any other 22 risk factors that have a different impact on a 23 specific subtype of ovarian cancer as opposed to 24 another subtype? 25 A. That is the only one that comes to mind.</p>
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<p>1 more questions. Okay? 2 THE VIDEOGRAPHER: Mr. James. 3 MR. JAMES: Oh, of course. 4 Can we go off just for one second? 5 How long did Ms. Parfitt go? 6 THE VIDEOGRAPHER: Going off record at 7 6:22 p.m. 8 (Discussion off the record.) 9 THE VIDEOGRAPHER: Back on record at 10 6:23 p.m. 11 FURTHER EXAMINATION BY COUNSEL FOR THE 12 JOHNSON & JOHNSON DEFENDANTS 13 BY MR. JAMES: 14 Q. Dr. Moorman, since the IARC published its 15 monograph in 2010, we have had the publication of 16 additional cohort data on the talc ovarian cancer 17 association; correct? 18 A. Correct. 19 Q. With regard to the subtypes issue, do you 20 believe that different subtypes of ovarian cancer have 21 different risk profiles? 22 MS. PARFITT: Objection. Form. 23 You can answer. 24 BY MR. JAMES: 25 Q. And I'm talking about in general.</p>	<p>1 MR. JAMES: That's all I have. Thank 2 you again for your time. 3 THE WITNESS: Okay. 4 MS. PARFITT: Thank you. 5 THE VIDEOGRAPHER: This concludes the 6 deposition of Dr. Patricia Moorman. The time going 7 off record is 6:25 p.m. 8 (Whereupon, at 6:25 p.m., the deposition ceased. 9 Signature was reserved.) 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>

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<p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2 I, PATRICIA G. MOORMAN, M.S.P.H., PH.D., do</p> <p>3 hereby acknowledge that I have read and examined the</p> <p>4 foregoing testimony, and the same is a true, correct,</p> <p>5 and complete transcription of the testimony given by me,</p> <p>6 and any corrections appear on the attached errata sheet</p> <p>7 signed by me.</p> <p>8</p> <p>9</p> <p>10 _____</p> <p>11 (DATE) (SIGNATURE)</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 STATE OF NORTH CAROLINA)</p> <p>2) CERTIFICATE</p> <p>3 COUNTY OF ORANGE)</p> <p>4 I, Sophie Brock, Court Reporter and Notary Public,</p> <p>5 the officer before whom the foregoing proceeding was</p> <p>6 conducted, do hereby certify that the witness(es) whose</p> <p>7 testimony appears in the foregoing proceeding were duly</p> <p>8 sworn by me; that the testimony of said witness(es) were</p> <p>9 taken by me to the best of my ability and thereafter</p> <p>10 transcribed under my supervision; and that the foregoing</p> <p>11 pages, inclusive, constitute a true and accurate</p> <p>12 transcription of the testimony of the witness(es).</p> <p>13 I do further certify that I am neither counsel for,</p> <p>14 related to, nor employed by any of the parties to this</p> <p>15 action, and further, that I am not a relative or</p> <p>16 employee of any attorney or counsel employed by the</p> <p>17 parties thereof, nor financially or otherwise interested</p> <p>18 in the outcome of said action.</p> <p>19 This, the 26th day of January, 2019.</p> <p>20</p> <p>21</p> <p>22 _____</p> <p>23 Sophie Brock, RDR, CRR</p> <p>24 Notary Number: 200834000001</p> <p>25</p>																																																																																				
<p>Page 319</p> <p>1 ERRATA</p> <p>2 CASE NAME: TALCUM POWDER LITIGATION MDL NO. 2738</p> <p>3 WITNESS NAME: PATRICIA G. MOORMAN, M.S.P.H., PH.D.</p> <p>4 CASE NUMBER: 16-2738 (FLW)(LHG)</p> <table border="1"><thead><tr><th>5</th><th>PAGE LINE</th><th>READS</th><th>SHOULD READ</th></tr></thead><tbody><tr><td>6</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>7</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>8</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>9</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>10</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>11</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>12</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>13</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>14</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>15</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>16</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>17</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>18</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>19</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>20</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>21</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>22</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>23</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>24</td><td>_____</td><td>_____</td><td>_____</td></tr><tr><td>25</td><td>_____</td><td>_____</td><td>_____</td></tr></tbody></table>	5	PAGE LINE	READS	SHOULD READ	6	_____	_____	_____	7	_____	_____	_____	8	_____	_____	_____	9	_____	_____	_____	10	_____	_____	_____	11	_____	_____	_____	12	_____	_____	_____	13	_____	_____	_____	14	_____	_____	_____	15	_____	_____	_____	16	_____	_____	_____	17	_____	_____	_____	18	_____	_____	_____	19	_____	_____	_____	20	_____	_____	_____	21	_____	_____	_____	22	_____	_____	_____	23	_____	_____	_____	24	_____	_____	_____	25	_____	_____	_____	
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